Federal Court of Australia

Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd (No 4) [2021] FCA 416

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| File numbers: | NSD 121 of 2012  NSD 837 of 2015 |
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| Judgment of: | **YATES J** |
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| Date of judgment: | 27 April 2021 |
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| Catchwords: | **PRACTICE AND PROCEDURE** – application for additional discovery |
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| Legislation: | *National Health Act 1953* (Cth) s 99ACB  *Federal Court Rules 2011* (Cth) rr 20.11, 20.15  *Federal Court of Australia Act 1976* (Cth) s 37M |
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| Cases cited: | *Benjoy Berry v CCL Secure Pty Ltd* [2020] HCA 27; 381 ALR 427  *Malec v JC Hutton Pty Ltd* [1990] HCA 20; 169 CLR 638  *Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd* [2012] FCA 239  *Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd* [2019] FCA 230  *Sellars v Adelaide Petroleum NL* [1994] HCA 4; 179 CLR 332  *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2018] FCA 1556; 136 IPR 8 |
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| Date of hearing: | 8 March 2021 |
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| Counsel for the Applicants: | Mr J Hutton |
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| Solicitors for the Applicants: | Jones Day |
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| Counsel for the Respondents: | Mr P Knowles |
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| Solicitors for the Respondents: | Corrs Chambers Westgarth |

ORDERS

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|  | | NSD 121 of 2012 |
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| BETWEEN: | OTSUKA PHARMACEUTICAL CO., LTD  First Applicant/First Appellant  BRISTOL-MYERS SQUIBB COMPANY  Second Applicant/Second Appellant | |
| AND: | GENERIC HEALTH PTY LTD (ACN 110 617 859)  First Respondent  COMMONWEALTH OF AUSTRALIA  Other | |

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| order made by: | YATES J |
| DATE OF ORDER: | 27 april 2021 |

THE COURT ORDERS THAT:

1. The interlocutory application for additional discovery dated 22 December 2020 and filed by Otsuka Pharmaceutical Co., Ltd and Bristol-Myers Squibb Company be dismissed, with costs.

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

ORDERS

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|  | | NSD 837 of 2015 |
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| BETWEEN: | OTSUKA PHARMACEUTICAL CO., LTD  First Applicant/First Appellant  BRISTOL-MYERS SQUIBB COMPANY  Second Applicant/Second Appellant | |
| AND: | GENERIC HEALTH PTY LTD (ACN 110 617 859)  First Respondent  COMMONWEALTH OF AUSTRALIA  Other | |

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REASONS FOR JUDGMENT

YATES J:

# Introduction

1. This is an application for additional discovery made in proceedings NSD 121/2012 and NSD 837/2015 in which the Commonwealth of Australia (the **Commonwealth**) has applied to enforce various undertakings as to damages given by Otsuka Pharmaceutical Co. Ltd, and Bristol-Myers Squibb Company (together, **Otsuka/BMS**). Separately, Generic Health Pty Ltd (**Generic Health**) has applied to enforce these undertakings.
2. The background to the enforcement applications is explained in *Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd* [2019] FCA 230. For present purposes, the relevant facts include the following.
3. On or about 29 November 2011, Generic Health applied to have its aripiprazole products listed on the Pharmaceutical Benefits Scheme (**PBS**) with effect from 1 April 2012. However, on 23 February 2012, Otsuka/BMS applied for an interlocutory injunction restraining Generic Health from engaging in certain conduct in relation to those products because of threatened infringement of Patent No. 2005201772 (the **patent**). The relief claimed included an order that Generic Health withdraw its application to list its aripiprazole products on the PBS.
4. On 16 March 2012, the application for the interlocutory injunction was determined in favour of Otsuka/BMS: *Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd* [2012] FCA 239. On 22 March 2012, an interlocutory injunction was granted requiring Generic Health to withdraw its PBS application subject to Otsuka/BMS giving an undertaking as to damages.
5. On or about 19 March 2012, after knowing of the result of the interlocutory hearing, but before the interlocutory injunction was granted, Generic Health withdrew its application for PBS listing.
6. As events transpired, the patent was found to be invalid. But the interlocutory injunction was effectively continued. The interlocutory injunction remained in operation until 4.00 pm on 21 September 2016.
7. On 4 September 2019, orders for discovery were made in the Commonwealth’s enforcement applications, following a contested hearing before a Registrar of the Court. The Commonwealth was ordered to give discovery in respect of 24 categories of documents (the **existing categories for discovery**). The issues to which these documents relate include:
   1. whether, had the interlocutory injunction not been granted, Generic Health would have maintained its application to list its aripiprazole products on the PBS, and
   2. whether, had the listing application been maintained, those products would have been listed by the Minister for Health.
8. Discovery, according to these categories, was given in four tranches on 30 June 2020, 14 October 2020, 4 December 2020, and 29 January 2021.
9. By an interlocutory application filed on 22 December 2020, Otsuka/BMS now seek additional discovery from the Commonwealth pursuant to r 20.15 of the *Federal Court Rules 2011* (Cth) (**FCR**) by reference to five categories of documents.
10. As to these, two categories concern documents relating to PBS listing applications by Generic Health other than in relation to Generic Health’s aripiprazole products in issue in the principal proceedings. Two categories seek documents relating to the approach taken by the Department of Health (the **Department**) when a supplier of a PBS-listed pharmaceutical product has been unable to supply the product on the day of its listing. The final category seeks documents that record modelling or consideration by the Commonwealth of the effect on the expenditure on the PBS for aripiprazole of market entry by other pharmaceutical products indicated for the treatment of schizophrenia.
11. The Commonwealth opposes Otsuka/BMS’s application.
12. The documents discovered by reference to the existing categories for discovery were sourced from electronic and hard copy records maintained by the Department. Most of the hard copy records were digitised for this purpose. However, some of the Commonwealth’s records were unable to be digitised, or were not digitised because of time constraints. These records were, therefore, reviewed in hard copy. The giving of this discovery required approximately 900 hours of work by officers within the Department and approximately 409.6 hours of work by the Commonwealth’s solicitors. Not included in these figures is the time spent by officers working in the Therapeutic Goods Administration and in other agencies of the Commonwealth, who were also involved in the discovery process.
13. The documents held by the Department that relate to applications for the listing of products on the PBS are primarily contained in listing files and pricing files maintained by reference to the person who is seeking that listing (referred to as the “responsible person” in the *National Health Act 1953* (Cth) (**NHA**)). These files are kept in a mix of hard copy and electronic formats. The documents may also be in the form of hard copy documents called “listing cards” or found in group email boxes maintained by the PBS Listing and PBS Pricing teams within the Department. In order to give discovery in the existing categories for discovery, the Commonwealth searched documents in these repositories in relation to 37 companies in addition to documents in relation to Generic Health.

# The general position of the parties

## Otsuka/BMS

1. Otsuka/BMS advance four general reasons why their application for additional discovery should be granted.
2. First, Otsuka/BMS submit that four of the five proposed additional categories are directed to the two factual issues I have identified at [7] above. Otsuka/BMS argue that these are key factual issues in the Commonwealth’s claim, which exceeds $110 million.
3. Secondly, the additional discovery is, according to Otsuka/BMS, directed to “new developments”, namely:
   1. the filing, in June 2020, of affidavits by Generic Health which describe what Generic Health says it would have done had the interlocutory injunction not been granted: see, in that regard, Exhibit A, which is an extract from the affidavit of Sofia Mumtaz made 8 June 2020; and
   2. the filing, on 20 November 2020, of new points of claim by the Commonwealth in which it pleads an alternative claim for loss of opportunity—the loss of opportunity of Generic Health to supply its aripiprazole products on the PBS and the consequent and coordinate loss of opportunity of the Commonwealth to list those products on the PBS, and thus reduce the cost of aripiprazole products borne by the Commonwealth.
4. Thirdly, as the Commonwealth has digitised most of its hard copy files in order to give discovery by reference to the existing categories for discovery, the burden of reviewing documents for the purpose of the additional discovery sought could be reduced by deploying “commonly used electronic searching tools”. Thus, Otsuka/BMS argue that the burden of complying with the additional discovery they seek would be proportionate to the complexity and magnitude of the Commonwealth’s claim.
5. Fourthly, as no trial date has been set, any prejudice to the Commonwealth will be limited to costs and will not cause delay to the existing timetable for the proceedings, noting that the only existing timetabling orders are for Generic Health and the Commonwealth to file lay accounting evidence and expert evidence by 21 May 2021.

## The Commonwealth

1. In addressing the four general reasons advanced by Otsuka/BMS to justify additional discovery, the Commonwealth draws attention, firstly, to r 20.11 FCR which provides that a party must not apply for an order for discovery unless the making of the order will facilitate the just resolution of the proceeding as quickly, inexpensively, and efficiently as possible. I observe that this rule is an exemplification of the requirement of s 37M of the *Federal Court of Australia Act 1976* (Cth) (the **Federal Court Act**) that the Court’s civil practice and procedure provisions must be interpreted and applied in the way that best promotes the overarching purpose stated in s 37M(1).
2. The Commonwealth submits that, consistently with r 20.11, the Court must be vigilant to ensure that excessive and wasteful discovery does not occur, particularly in circumstances where a party, as here, is being asked to undertake discovery a second time, after extensive discovery has already been given.
3. As I have noted, Otsuka/BMS seeks the additional discovery on the basis that it will address the two factual issues I have identified above at [7]. The Commonwealth does not dispute this proposition. It submits, however, that, as a matter of general approach, the real question is not whether the additional discovery that is now sought is adjectivally relevant to those issues, but whether the additional discovery is sufficiently relevant to justify the expense and inconvenience involved.
4. As to these matters, the Commonwealth points out that the categories of documents for which additional discovery is sought are not limited to the aripiprazole products in issue in the proceedings, but extend to other (any) pharmaceutical products. The Commonwealth submits that the relevance of the documents in the additional categories depends on an assumption that conduct in respect of other products can logically inform the conduct of key actors in respect of aripiprazole. The Commonwealth submits that, for this reason, it cannot be assumed that documents captured by the additional categories, as they relate to other products, will be centrally relevant to the determination of the key issues in these proceedings.
5. Next, the Commonwealth disputes that the “new developments” to which Otsuka/BMS refer justifies the giving of additional discovery.
6. First, the Commonwealth submits that the two issues on which Otsuka/BMS rely as warranting additional discovery are not new issues but existing issues of which their legal advisers must have been aware when discovery was originally sought by reference to the existing categories. The Commonwealth submits that the evidence filed by Otsuka/BMS in support of the present application does not suggest otherwise.
7. Secondly, although Generic Health has filed additional evidence as to what it would have done had the interlocutory injunction not been granted, this does not mean that the two issues themselves have changed.
8. Thirdly, although the Commonwealth has filed new points of claim in which it pleads a claim for loss of opportunity, the new points of claim do not, in substance, raise a new claim. Rather, they provide for an assessment of past hypothetical events on the basis of possibilities, as an alternative to an assessment on the balance of probabilities: *Malec v JC Hutton Pty Ltd* [1990] HCA 20; 169 CLR 638; *Sellars v Adelaide Petroleum NL* [1994] HCA 4; 179 CLR 332.
9. Next, the Commonwealth submits that the burden of undertaking the additional discovery would be significant. The Commonwealth’s solicitor, Mr Korbel, has deposed that it will take approximately 16 weeks to conduct the searches and collate the documents potentially falling within the additional categories. This estimate assumes the involvement of seven departmental officers in carrying out searches and conducting a high-level review of the documents that might be located.
10. The documents will then need to be loaded into an electronic database and reviewed by solicitors in Mr Korbel’s firm to identify, firstly, whether the documents do fall within the proposed categories and, secondly, to identify any privilege claims attached to those documents.
11. Mr Korbel estimates that the total time necessary to undertake the additional discovery will be at least seven months. I have no reason to doubt Mr Korbel’s estimate. Mr Korbel has not deposed to the likely cost of this work but, on the basis of Mr Korbel’s description of the work involved, I infer that the cost will be very significant.
12. The Commonwealth submits that it is no answer for Otsuka/BMS to say that the burden of undertaking the additional discovery can be met by an order for costs. The tendency of discovery to significantly increase the cost of litigation is precisely the question raised by r 20.11 and, I would add, s 37M of the Federal Court Act.

# The additional categories

1. Having noted the general position of the parties in relation to the present application, it is now convenient to turn to each of the additional categories of documents for which discovery is sought. The parties treated proposed categories 28 and 29 together, and proposed categories 30 and 31 together.

## Proposed categories 28 and 29

1. In substance, proposed category 28 seeks applications made by Generic Health for PBS listing between 1 January 2010 and 31 December 2016, in circumstances where the listing triggered or would have triggered a statutory price reduction under s 99ACB of the NHA.
2. In substance, category 29 seeks documents “constituting, recording or referring to” communications between Generic Health and the Department concerning the withdrawal, by Generic Health, of any PBS listing application it made, in circumstances where the listing triggered or would have triggered the statutory price reduction, and where the withdrawal was for a reason other than the existence of an injunction restraining supply.
3. Otsuka/BMS contend that these categories relate to the question whether, had the interlocutory injunction not been granted, Generic Health would have maintained its application to list its aripiprazole products on the PBS. More specifically, they wish to challenge the proposition that, at the relevant time, Generic Health was a supplier who launched pharmaceutical products “at risk” (i.e., in the face of asserted patent rights). Indeed, Otsuka/BMS wish to explore whether Generic Health had a very different strategy of *avoiding* risk, by threatening to launch allegedly infringing products with a view to provoking the patentee to apply for and obtain an interlocutory injunction supported by an undertaking as to damages. Otsuka/BMS contend that this case theory is supported by observations made by Jagot J in *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2018] FCA 1556; 136 IPR 8 at [733] – [735].
4. In addition, Otsuka/BMS contend that, because of the Commonwealth’s amendment of its points of claim, this issue will now fall to be determined on the basis of possibilities, and not just on the balance of probabilities.
5. I do not accept that either of these matters justifies the giving of additional discovery by the Commonwealth with reference to these proposed categories. The case theory that Otsuka/BMS wish to pursue must have been known to them at the time when discovery was originally sought against the Commonwealth in these proceedings. Had they wished to pursue this case theory, they should have, and could have, sought discovery by reference to proposed categories 28 and 29 at that time—not now after extensive discovery has already been given by the Commonwealth with respect to the existing categories for discovery. The existing categories for discovery include, for example, documents dated or created in the period 18 November 2011 to 2 March 2018 referring to or recording communications between Generic Health and the Department (including certain specified agencies) or IP Australia concerning: the patent; proceedings NSD 121/2012 and NSD 837/2015; and/or Generic Health’s alleged infringement of the patent: see category 3.
6. Mr Korbel’s evidence, which I accept, is that, in order to give discovery in relation to proposed categories 28 and 29, it will be necessary for the Commonwealth to search again, and re-review, documents it has already searched and reviewed for the purpose of producing documents falling within the existing categories for discovery. Mr Korbel has deposed that, while some of the documents will exist in electronic form (including digitised versions of hard copy documents), the burden of giving discovery in respect of these proposed categories will not be significantly lessened. This is because:
   1. the proposed categories relate to applications made regardless of whether listing was achieved (meaning that searches cannot be limited to records of pharmaceutical products actually listed on the PBS);
   2. the Department does not maintain a central or separate record of applications for listing which do not proceed to actual listing;
   3. in relation to proposed category 29, the search for documents cannot be limited to so-called “trigger dates” within the stated period; and
   4. in relation to proposed category 29, the searching task is made more burdensome by the category’s reference to documents that constitute, record, or refer to withdrawals of PBS listing applications in the stated period.
7. I do not accept that additional discovery with reference to these proposed categories should be considered in a different light simply because the case theory that Otsuka/BMS wish to pursue will also fall to be determined according to possibilities, and not simply on the balance of probabilities.
8. I therefore decline to order the Commonwealth to give additional discovery with respect to these categories.
9. I note that, in any event, on 19 February 2021, the Court made orders by consent that Generic Health give additional discovery of documents in categories that mirror proposed categories 28 and 29. Otsuka/BMS will have the benefit of this discovery and, to the extent that it might be necessary to do so, they can seek leave to rely, in the Commonwealth’s enforcement proceedings, on the documents that will be discovered by Generic Health under this order. Otsuka’s/BMS’s contention that they should be able “to consider the Commonwealth’s side of the documentation” in relation to these categories, and their speculative suggestion that Generic Health may not have kept complete records, do not justify the further burden they now wish to place upon the Commonwealth, and certainly do not change the conclusion I have expressed at [39] above.

## Proposed categories 30 and 31

1. In substance, proposed category 30 seeks documents “constituting, recording or referring to” communications between the Department (including certain specified agencies) or IP Australia, and any supplier of pharmaceutical products, regarding the supplier’s inability to supply a product on the day of its PBS listing, where the listing triggered or would have triggered the statutory price deduction, and where the document is dated or created within the period 1 January 2011 and 31 December 2016.
2. In substance, proposed category 31 seeks a range of documents created in the same period as category 30—specifically, all websites, forms, publications, policies, process documents, manuals, listing unit requirements, guidelines or guidance notes—which address a supplier’s inability to supply a pharmaceutical product on the day of its PBS listing, where the listing triggered or would have triggered the statutory price reduction.
3. Otsuka/BMS contend that documents in these categories will shed light on whether, and the extent to which, in deciding whether or not to approve an application for PBS listing, the Commonwealth takes into account the ability of the responsible person to supply the relevant product.
4. More specifically, Otsuka/BMS point to the fact that Generic Health has filed an affidavit (Tanya Leanne Lovett made 9 June 2020) which states that its aripiprazole products would have become available from the end of March 2012 to the second week of April 2012 (i.e., in a period after the nominated listing date of 1 April 2012) and that it was Ms Lovett’s expectation that any delay in supply, of this order, would not have caused the Department to “withdraw” the listing of Generic Health’s aripiprazole products on the PBS.
5. Therefore, Otsuka/BMS contend that the documents in proposed categories 30 and 31 are relevant to testing whether—but for the granting of the interlocutory injunction, and assuming Generic Health would have maintained its listing application—the Department would have approved the listing of Generic Health’s aripiprazole products, when Generic Health could not guarantee supply of those products on and from 1 April 2012.
6. I note that, at the time that Otsuka/BMS originally sought discovery against the Commonwealth in these proceedings, Generic Health’s possible inability to supply its aripiprazole products on and from the nominated listing date of 1 April 2012 was already raised in filed affidavits. Therefore, this issue is not one that has been recently raised. Indeed, the existing categories for discovery by the Commonwealth include all documents provided to or created by the Department or the Minister, dated or created between 18 November 2011 and 1 December 2016, which record information concerning Generic Health’s ability to supply all or any of its aripiprazole products from 1 April 2012: see category 4.
7. Proposed category 30 is not limited to aripiprazole products; nor is it limited to PBS applications by Generic Health. It covers the gamut of pharmaceutical products for which PBS listing was sought in the nominated six-year period.
8. Further, in relation to this category:
   1. the assumption is that applications concerning other pharmaceutical products (including those completely unrelated to aripiprazole or the class of drugs to which it belongs) made in other circumstances, by other responsible persons, are capable of informing a decision by the Department about the PBS listing of Generic Health’s aripiprazole products in the particular circumstances of the present case;
   2. the documents sought are not limited to successful PBS applications, but concern all PBS applications, whether successful or not; and
   3. the documents are not limited to applications made by any particular responsible person.
9. Therefore, if discovery were to be ordered with respect to this proposed category, the Commonwealth would be required to search its repositories of documents covering a six-year period, in respect of every responsible person who has sought to list any branded pharmaceutical product on the PBS. The onerous nature of this task would be exacerbated by the requirement to discover documents that constitute, record, or refer to the communications in question.
10. Mr Korbel’s evidence, which, once again, I accept, is that the search for documents covered by proposed category 30 would be far more extensive than that already carried out by the Commonwealth in respect of the existing categories for discovery, and will also require the Commonwealth to search again, and review, documents that it has already searched and reviewed for the purposes of the discovery it has given.
11. I am not persuaded that other applications for the PBS listing of other pharmaceutical products, by other responsible persons, made in other circumstances, are likely to be anything but of the most marginal relevance to the present case. Discovery with reference to proposed category 30 would involve a significant retracing of steps and re-examination of documents already searched for and examined. Given those facts, I am not persuaded that the significant burden that would be placed on the Commonwealth in giving additional discovery with respect to this category is warranted or justified, particularly in circumstances where no explanation has been given as to why such discovery, assuming it to be otherwise appropriate, was not sought when discovery by the Commonwealth was originally ordered.
12. I also note that, in accordance with the consent orders made on 19 February 2021, Generic Health will give additional discovery of documents “constituting, recording, or referring to” communications between it and the Department regarding its inability to supply a pharmaceutical product (i.e., not limited to its aripiprazole products) on the day of its PBS listing, where the listing triggered or would have triggered the statutory price deduction, and where the document is dated or created within the period 1 January 2011 and 31 December 2016
13. Once again, Otsuka/BMS will have the benefit of this discovery and, to the extent that it might be necessary to do so, they can seek leave to rely, in the Commonwealth’s enforcement proceedings, on these documents that will be discovered by Generic Health.
14. As to proposed category 31, I note that categories 11, 12, and 13 of the existing categories of documents cover a range of policy documents dealing with PBS matters. In particular, category 11, in respect of which discovery has already been given, is directed to the following documents:

All websites, forms, publications, policies, process documents, manuals, listing unit requirements, guidelines or guidance notes dated or created between 9 July 2009 and 1 December 2017 (inclusive) addressing any of the following:

(a) the process for obtaining listing on the PBS Schedule, including listing of a new brand of an existing pharmaceutical item under s 85(6) of the NHA;

(b) the receipt and processing of applications for listing of a new brand of an existing pharmaceutical item under s 85(6) of the NHA by the Department, PBAC and/or PBPA;

(c) administrative practices of the Department, PBAC and/or PBPA relating to applications for listing on the PBS Schedule of a new brand of an existing pharmaceutical item under s 85(6) of the NHA;

(d) the extent to which consideration is or should be given by the Department, the Minister (or his or her delegate), PBAC and/or PBPA to the status of an unrevoked patent in respect of an existing pharmaceutical item when assessing an application to list a new brand of the existing pharmaceutical item under s 85(6) of the NHA;

(e) the Commonwealth’s ability to claim compensation from a pharmaceutical manufacturer who obtains an interlocutory injunction in patent litigation; and/or

(f) the operation of statutory price reductions, price disclosure and/or guarantee of supply obligations.

1. The evidence before me is that many of the Department’s forms, publications, policies, process documents, manuals, listing unit requirements, guidelines and guidance notes regarding the operation of the PBS are publicly available and published on the PBS-specific website maintained by the Department.
2. In order to locate the documents falling within existing category 11, the Commonwealth identified about 89 monthly offline copies of the PBS website in the period between July 2009 and December 2017, which were then produced to Otsuka/BMS. The Department also conducted searches of its electronic records, and made enquiries of staff, to identify any other documents which were not published on the PBS website, so as to comply with its discovery obligation in respect of this category.
3. There is an obvious overlap between the call of proposed category 31, and the call of category 11. I refer, in particular, to category 11(f). Otsuka/BMS have offered no explanation as to why existing category 11 is deficient and, if it is, why that deficiency was not addressed at the time when discovery by the Commonwealth was originally ordered.
4. I accept that, if the Commonwealth is ordered to give discovery with respect to proposed category 31, it is likely that the Department will need to make the same enquiries and conduct the same searches it has already undertaken for the purpose of giving discovery with reference to category 11. Given that fact, and the unexplained, belated nature of the present request, I am not persuaded that additional discovery in accordance with proposed category 31 is warranted or justified.
5. I therefore decline to order the Commonwealth to give additional discovery with respect to proposed categories 30 and 31.

## Proposed category 32

1. Proposed category 32 seeks documents dated on or after 1 January 2011 recording any modelling or consideration by the Commonwealth of how entry into the market of pharmaceutical products indicated for the treatment of schizophrenia (other than aripiprazole) would affect expenditure on the PBS in relation to aripiprazole.
2. Otsuka/BMS contend that documents sought by this category are relevant to determining the forecasted volume of aripiprazole supplied under the PBS (including the impact of other drugs indicated for the treatment of schizophrenia on the market for aripiprazole), which is, in turn, relevant to assessing the quantum of the Commonwealth’s claim loss. Otsuka/BMS contend that the documents answering this category are likely to be limited and that any burden imposed on the Commonwealth is proportionate to the size of its claim.
3. I have not been taken to any material which suggests that the supply of other pharmaceutical products indicated for the treatment of schizophrenia would affect either the quantity or value of aripiprazole supplied or to be supplied under the PBS. Further, and importantly, Otsuka/BMS have not pleaded any counterfactual case which raises this as an issue: see the observations of Gageler and Edelman JJ in *Benjoy Berry v CCL Secure Pty Ltd* [2020] HCA 27; 381 ALR 427 at [72] concerning the expectation that competing counterfactuals will be pleaded. If there were a proper basis for contending that the market entry of other pharmaceutical products indicated for the treatment of schizophrenia would affect expenditure on the PBS in relation to aripiprazole, then I would have expected Otsuka/BMS to have laid a proper factual foundation for that claim. They have not done so.
4. In the circumstances, I decline to order the Commonwealth to give additional discovery with respect to proposed category 32.

# Disposition

1. The interlocutory application for additional discovery dated 22 December 2020 and filed by Otsuka Pharmaceutical Co., Ltd and Bristol-Myers Squibb Company will be dismissed, with costs.

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| I certify that the preceding sixty-four (64) numbered paragraphs are a true copy of the Reasons for Judgment of the Honourable Justice Yates. |

Associate:

Dated: 27 April 2021