NOTICE OF FILING AND HEARING

This document was lodged electronically in the FEDERAL COURT OF AUSTRALIA (FCA) on 12/02/2019 3:48:58 PM AEDT and has been accepted for filing under the Court's Rules. Filing and hearing details follow and important additional information about these are set out below.

Filing and Hearing Details

Document Lodged**:**	Notice of Appeal (Fee for Leave Not Already Paid) - Form 122 - Rule 36.01(1)(b)(c)
File Number:	NSD182/2019
File Title:	MYLAN HEALTH PTY LTD & ANOR v SUN PHARMA ANZ PTY LTD & ANOR
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA
Reason for Listing:	To Be Advised
Time and date for hearing:	To Be Advised
Place:	To Be Advised

Dated**:** 13/02/2019 10:29:06 AM AEDT Registrar

Important Information

As required by the Court's Rules, this Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

The Reason for Listing shown above is descriptive and does not limit the issues that might be dealt with, or the orders that might be made, at the hearing.

The date and time of lodgment also shown above are the date and time that the document was received by the Court. Under the Court's Rules the date of filing of the document is the day it was lodged (if that is a business day for the Registry which accepts it and the document was received by 4.30 pm local time at that Registry) or otherwise the next working day for that Registry.

Form 122
Rules 36.01(1)(b); 36.01(1)(c)

Notice of appeal

No. ..... of 2019

Federal Court of Australia

District Registry: New South Wales

Division: General

On appeal from the Federal Court

Mylan Health Pty Ltd and another named in the schedule

Appellants

Sun Pharma ANZ Pty Ltd and another named in the schedule

Respondents

To the Respondents

The Appellants appeal from the judgment as set out in this notice of appeal.

1. The papers in the appeal will be settled and prepared in accordance with the Federal Court Rules Division 36.5.

2. The Court will make orders for the conduct of the proceeding, at the time and place stated below. If you or your lawyer do not attend, then the Court may make orders in your absence. You must file a notice of address for service (Form 10) in the Registry before attending Court or taking any other steps in the proceeding.

Time and date for hearing:

Place:

Federal Court of Australia
Queens Square, Sydney NSW 2000

Filed on behalf of (name & role of party) Mylan Health Pty Ltd and another, the Appellants
Prepared by (name of person/lawyer) Shyama Jayaswal
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Our reference: 1102803

Date:

Signed by an officer acting with the authority
of the District Registrar

The Appellants appeal from orders 1 to 4 and 8 of the Federal Court given on 22 January 2019 at Sydney.

Grounds of appeal

In this notice of appeal, the following defined terms having the following meanings:

(a) the **Act** means the Patents Act 1990 (Cth);

(b) the **711 Patent** means Australian patent number 2006313711;

(c) the **964 Patent** means Australian patent number 731964;

(d) the **807 Patent** means Australian patent number 2003301807;

(e) the **Patents** mean the 711 Patent, the 964 Patent and the 807 Patent;

(f) the **Ranbaxy Products** mean the products having the following Australian Register of Therapeutic Goods (**ARTG**) entry numbers:

(i) 233498 for FENOFIBRATE RBX 145 mg fenofibrate film coated tablets bottle;

(ii) 233497 for FENOFIBRATE RAN 145 mg fenofibrate film coated tablets blister pack;

(iii) 233496 for FENOFIBRATE SUN 145 mg fenofibrate film coated tablets blister pack;

(iv) 233495 for FENOFIBRATE RAN 145 mg fenofibrate film coated tablets bottle;

(v) 233492 for FENOFIBRATE RBX 145 mg fenofibrate film coated tablets blister pack; and

(vi) 233488 for FENOFIBRATE SUN 145 mg fenofibrate film coated tablets bottle.

Furthermore, in this notice of appeal, paragraph references are to the reasons of the primary judge, and are not intended to be exhaustive.

THE 711 PATENT

Infringement of Swiss-style claims (claims 1, 5 and 6)

1. The primary judge erred in finding that claims 1, 5 and 6 of the 711 Patent (collectively, the **Swiss-style claims**) had not been or would not be infringed by the First Respondent (at [106]).

2. The primary judge erred in finding that infringement of the Swiss-style claims required a "mental element", namely, the manufacturer of the relevant medicament must be shown to have an "objective intention" that the medicament would be used to treat the medical condition designated in the claim (at [98], [101], [102], [103], [106]).

3. Alternatively to ground 2 above, insofar as infringement of the Swiss-style claims requires the manufacturer of the relevant medicament to have an "objective intention" that the medicament would be used to treat the medical condition designated in the claim as held by the primary judge, then, his Honour erred in finding that the evidence did not support a finding that the Ranbaxy Products had been, or will be, manufactured with the "objective intention" that they be used for the prevention or treatment of diabetic retinopathy (at [102] to [106]).

4. Alternatively to ground 2 above, having found that the First Respondent had reason to believe that a significant portion of the Ranbaxy Products that it proposes to supply will be used in a manner which would infringe, *inter alia*, claims 7, 10, 11 and 12 of the 711 Patent (at [118]), his Honour erred in finding that the evidence did not support a finding that the Ranbaxy Products had been, or will be, manufactured with the "objective intention" that they be used for the prevention or treatment of diabetic retinopathy (at [102] to [106]).

Novelty in light of the Protocol (claims 1, 5, 6, 7, 10, 11 and 12)

5. The primary judge erred in finding that claims 1, 5, 6, 7, 10, 11 and 12 of the 711 Patent (collectively, the **711 Claims**) are invalid for lack of novelty in light of the Protocol for the Eye Study dated 30 January 2004 (the **Protocol**) (at [164]).

6. Having found that the Protocol identifies:

   (a) the "second aim of the study" as including the statement "… will the addition of fibrate therapy [to statin therapy]…decrease the risk of [diabetic retinopathy]?" (at [156]); and

   (b) the second "hypothesis for the study" (at [157]),

   the primary judge erred in finding (at [162]) that the Protocol suggested that fenofibrate "could be used" for the prevention and treatment of diabetic retinopathy. The primary judge ought to have found that the Protocol did no more than articulate a "hypothesis" that may or may not be correct, which is not sufficient to anticipate a claim.

7. The primary judge erred in finding (at [164]) that:

   (a) "the Protocol clearly discloses a method of administering fenofibrate … in the expectation that this would reduce the risk of development or progression of diabetic retinopathy…"; and

   (b) the "[u]se of fibrate in accordance with this method would clearly infringe each of the method of treatment claims".

Novelty in light of Example 7 of the Squibb Patent (claims 1, 6, 7 and 12)

8. The primary judge erred in finding that claims 1, 6, 7 and 12 of the 711 Patent are invalid for lack of novelty in light of Example 7 of the Squibb Patent (**Example 7**) (at [169]).

9. The primary judge erred in failing to find that Example 7, when read in the context of the Squibb Patent, did not anticipate claims 1, 6, 7 and 12 of the 711 Patent, because the Squibb Patent only recited the use of a very large number of possible compounds, either by themselves or in combination with other agents, for the potential treatment of the entire range of complications of diabetes, including both macrovascular and microvascular complications, rather than providing a clear and unmistakeable direction to use fenofibrate therapy for the treatment of diabetic retinopathy (at [165] and cf [169]).

Inventive step in light of common general knowledge (claims 1, 5, 6, 7, 10, 11 and 12)

10. The primary judge erred in finding that the 711 Claims are invalid for lack of an inventive step in light of the common general knowledge (at [250]).

11. Having made the following findings:

(a) "[i]t was not common general knowledge that lipid lowering agents had a beneficial effect on the underlying causes of diabetic retinopathy" (at [221]);

(b) "…as at 10 November 2005, fibrates, including fenofibrate, were not prescribed for the treatment of hypercholesterolemia if target lipid levels could be achieved by the use of a statin unless there was some other reason why a patient's elevated lipid levels could not be treated with those drugs (eg. because of side effects)" (at [222]);

(c) "…ETDRS 22 did not, and was not designed to, determine whether lipid lowering agents could be used to reduce the risk of the development or progression of hard exudates or diabetic retinopathy more generally. Nor did it demonstrate a causative link between blood lipid levels and the development or progression of hard exudates" (at [228]);

(d) "[t]he ETDRS 22 was merely an observational study that was not designed to evaluate the effectiveness of any relevant pharmacological treatment on hard exudates or diabetic retinopathy more generally" (at [231]);

(e) "[s]tatins were the preferred, and most widely prescribed, lipid lowering drugs as at 10 November 2005" (at [231]);

(f) "[t]here were no pharmacological treatments that had been shown to prevent or slow the development of hard exudates or diabetic retinopathy more generally" (at [231]); and

(g) "…the authors of ETDRS 22 adjusted for certain variables … which was less than perfect, particularly if they were seeking to determine whether there is an association between elevated levels of triglycerides and retinal hard exudates that is independent of blood glucose levels. The difficulty stems from the fact that patients with high triglyceride levels generally have high blood glucose levels, which are known to be causally related to diabetic retinopathy. This may make it difficult to identify the existence of an independent association between triglycerides levels and hard exudates in circumstances where blood lipid levels were only measured at the commencement of the study." (at [236]),

the primary judge erred in finding that the notional skilled team would have been directly led by ETDRS 22 to try fenofibrate in combinations with statins in the expectation that

this might well prevent or slow the development or progression of retinal hard exudates (at [248]).

12. The primary judge erred by relying on ETDRS 22 as evidencing that the hypothetical person (or team) skilled in the art had the expectation that fenofibrate (whether alone or in combination with a statin) might well produce a useful or better alternative to other therapies used for the prevention or treatment of diabetic retinopathy (at [248], [249]).

13. The primary judge erred in answering the modified Cripps question in the affirmative (at [198] to [250]) by giving improper weight to the evidence of Beaumont and Carter, having made the following findings:

    (a) Dr Beaumont is the "…antithesis of the non-inventive worker in the field" (at [197]);

    (b) "…Professor Carter is not someone who I would consider uninventive" (at [230]); and

    (c) "[i]t is apparent that Professor Carter's thinking was very much informed not only by ETDRS 22, but also by various articles none of which was suggested to form part of the common general knowledge…" (at [239]).

14. The primary judge erred in finding that "[t]he modified Cripps question may receive an affirmative answer even if the hypothetical person (or team) skilled in the art has prospects of success that are less than fifty-fifty" (at [249]).

15. The primary judge erred in answering the modified Cripps question in the affirmative (at [249]) by failing to give any or sufficient weight to the evidence of Professor O'Brien that the prospect of fenofibrate proving effective in the treatment of diabetic retinopathy was "no better than fifty-fifty".

Injunctive relief (claims 7, 10, 11 and 12)

16. Having found that the First Respondent had reason to believe that a "significant portion" of the Ranbaxy Products that it proposes to supply will be used in a manner which would infringe claims 7, 10, 11 and 12 of the 711 Patent (at [118]), the primary judge erred in finding (at [259]) that if he had found those claims valid, he would have refused the injunctive relief sought by the Appellants.

17. The primary judge erred in finding (at [257]) that the fact that a new method of treatment involves using a therapeutic agent that is widely used for non-infringing purposes provides "a powerful argument in favour of refusing" a blanket injunction.

18. The primary judge erred in finding (at [259]) that if he had found claims 7, 10, 11 and 12 of the 711 Patent valid, he would have refused the injunctive relief sought by the Appellants in "light of the undertakings proffered by the [first] respondent and the extensive use of fenofibrate as a lipid-lowering agent" (the **First Respondent's proposed undertakings**).

19. The primary judge erred in finding that he would have refused the injunctive relief sought by the Appellants in circumstances where:

    (a) the First Respondent had first raised the scope of injunctive relief and the First Respondent's proposed undertakings as an issue in closing submissions at trial;

    (b) the First Respondent had not pleaded or otherwise put on evidence about the scope of injunctive relief or the utility of its proposed undertakings;

    (c) the Appellants had submitted in closing that, in the event the primary judge was not minded to award a blanket injunction with respect to the 711 Patent in light of the First Respondent's proposed undertakings, then the parties would need to address what appropriate relief should flow with further evidence and submissions; and

    (d) in light of the above, the Appellants were denied a proper opportunity to adduce evidence on the issue and address the issue by way of submission in light of that evidence.

20. The primary judge erred in finding (at [259]) that he would have refused the injunctive relief sought by the Appellants in circumstances where:

    (a) the primary judge found that the First Respondent has reason to believe that a "significant portion" of the Ranbaxy Products that it proposes to supply will be used in a manner which would infringe claims 7, 10, 11 and 12 of the 711 Patent (at [118]);

    (b) on the evidence before the primary judge, his Honour should have found that 50% of prescriptions for fenofibrate were written for the sole purpose of treating diabetic retinopathy and 20% for that and one or more other purposes; and

(c) the primary judge's finding (at [115]) that a "large proportion of the fenofibrate that is currently prescribed is for what should be considered non-infringing use" was contrary to the evidence.

Injunctive relief (claims 1, 5 and 6)

21. The primary judge erred in failing to find that, if he had found claims 1, 5 and 6 of the 711 Patent valid, he would have granted the injunctive relief sought by the Appellants.

THE 964 PATENT

Fair basis (claims 12 and 13)

22. The primary judge erred in finding that claims 12 and 13 of the 964 Patent are not fairly based on the matter described in the specification (at [290]).

23. The primary judge erred in failing to find that claims 12 and 13 are fairly based on the matter described in the specification when read as a whole, by reason of:

(a) the dissolution profile specified at page 5 lines 13-20; and

(b) the comparative studies at page 6 lines 8-14 describing "a composition according to the invention" and which are depicted in Figures 1 and 2.

The Saccharin doctrine (claims 17 and 19)

24. The primary judge erred in finding that the First Respondent did not threaten to infringe claims 17 and 19 of the 964 Patent (at [319]).

25. The primary judge erred in finding that the Saccharin doctrine does not form part of Australian law (at [311] to [319]).

26. The primary judge erred in failing to find that the phrase "in respect of a product resulting from such use" in sub-paragraph (b) of the definition of "exploit" in the Act includes a product resulting directly or indirectly from a claimed method and the importation of a product made using a claimed product is also an exploitation under sub-paragraph (a) of the definition of "exploit" in the Act.

THE 807 PATENT

Construction of claim 1 and 40 (and their dependent claims)

27. The primary judge erred in his construction of the term "composition" in claims 1, 2 and 3 and their dependent claims (at [352] to [366]) and claim 40, 41 and 42 and their dependent claims (at [369]) (the "**composition integer**").

28. The primary judge erred in finding that the composition integer means a composition in finished dosage form (eg. a tablet, capsule or oral suspension) suitable for oral administration (at [362]).

29. The primary judge erred in failing to find that the composition integer means a composition that is the stabilised fenofibrate nanoparticulate described in paragraphs (a) and (b) of claim 1, which is capable of being formulated for oral administration.

Infringement (the phospholipid integer)

30. The primary judge erred in failing to find that the Ranbaxy Products have the feature of paragraph (iii) of each of claims 1, 2 and 3 (and their dependent claims) (at [379]).

Inventive step in light of the common general knowledge (all asserted claims)

31. The primary judge erred in finding that claims 1 to 7, 9, 11, 12, 18 to 21, 23, 24, 26, 27, 31 to 32, 36 to 38, 40 to 45, 47, 49, 50, 56 to 59, 61, 62, 64, 65, 69 to 70, 74 to 76 and 78 to 80 of the 807 Patent (collectively, the **807 Claims**) are invalid for lack of an inventive step in light of the common general knowledge (at [419] to [428]).

32. The primary judge erred in considering and determining the question of whether the 807 Claims lack an inventive step in light of the common general knowledge alone (at [396] to [428]) in circumstances where:

    (a) the First Respondent did not adduce evidence from its experts that the 807 Claims lacked an inventive step in light of common general knowledge alone; rather, the First Respondent's evidence was directed to the issue of whether the 807 Claims lacked an inventive step when considered in light of the 704 Patent taken together with the common general knowledge;

    (b) as a result, the Appellants' evidence did not address whether the 807 Claims lacked an inventive step in light of common general knowledge alone;

(c) the experts were not cross-examined at trial on the issue of whether the 807 Claims lacked an inventive step in light of the common general knowledge alone, nor did they address such matters in the concurrent evidence session at trial;

(d) the case advanced by the First Respondent at trial was that the 807 Claims lacked an inventive step in light of the 704 Patent together with the common general knowledge, as identified in issue 13 (at [349]).

33. Having found that the 807 Claims did not lack an inventive step in light of the 704 Patent and the common general knowledge (at [428] to [445]), the primary judge erred in finding that the 807 Claims lacked an inventive step in light of the common general knowledge alone (at [403] to [419]).

34. The primary judge erred in finding that, the "notional team would know of the need for a new fenofibrate formulation suitable for oral administration that eliminated the food effect" and that this problem was common general knowledge (at [399] and [404]).

35. The primary judge erred in finding that, the "the notional team would try HPMC and SLS, both of which were commonly used in the formulation of pharmaceuticals to prevent or reduce particle agglomeration and to assist in dissolution" (at [408]).

36. The primary judge erred in finding that, based on Professor Roberts' evidence reproduced at [415], the notional team would have had an expectation of success in the sense required by the modified Cripps question (at [416]).

37. The primary judge erred in finding, based on Professor Roberts' evidence (reproduced at [415]), that the notional team would have had "a reasonable expectation … that a formulation that used HPMC and SLS to stabilize nanoparticles of fenofibrate would work, ie., they could be combined to produce a stable formulation of fenofibrate particles that were less than 300 nm in size and small enough to eliminate the food effect" (at [416]).

38. The primary judge erred in finding that the requisite expectation of success required by the modified Cripps question was satisfied by the evidence of Professor Roberts that he considered it to be a "gamble" whether or not a fenofibrate formulation that used a combination of HPMC and SLS would work (at [415], [416]).

39. Having found, based upon the evidence of Professors Prestidge and Roberts (reproduced at [391] and [392]), that "there are a number of factors that come into play when assessing whether the reductions in drug particle sizes will increase dissolution

rates and the food effect" (at [393]), the primary judge erred in failing to give any or sufficient weight to this evidence in answering the modified Cripps question, including the requirement as to the expectation of success.

Orders sought

1. The appeal be allowed.

2. Orders 1 to 4 and 8 of the Federal Court made on 22 January 2019 be set aside.

3. Further or alternatively, order 1 of the Federal Court made on 22 January 2019 be stayed:

   (a) initially for a period of 21 days; and

   (b) if an application to amend the claims of the 711 Patent is made within that period, until the final determination of that application or further order.

4. A declaration that the First Respondent threatened to infringe claims 1, 5 to 7, 10, 11 and 12 of the 711 Patent and claims 12, 13, 17 and 19 of the 964 Patent by threatening to import, manufacture, offer to make, use, offer for supply or sale, supply, sell, or keep for any of these purposes in Australia, the Ranbaxy Products.

5. An order that the First Respondent, whether by itself, its directors, officers, servants, agents or otherwise, be restrained during the term of the 711 Patent from, without the licence of the Appellants or either of them:

   (a) importing, manufacturing, offering to make, using, offering to supply, supplying, offering for sale, selling and keeping for any of the aforementioned purposes the Ranbaxy Products or any other pharmaceutical composition which includes the active ingredient fenofibrate falling within the claims of the 711 Patent (**Fenofibrate Product**);

   (b) causing the drug fenofibrate to move from the F1 formulary to the F2 formulary, including by obtaining listing in the Schedule of Pharmaceutical Benefits for the Ranbaxy Products or a Fenofibrate Product;

   (c) threatening to do any of the acts specified in orders (a) or (b) above; or

   (d) authorising any other person to do any of the acts specified in orders (a) or (b) above.

6. A certificate of validity pursuant to s 19 of the Act in respect of claims 1, 5 to 7, 10, 11 and 12 of the 711 Patent; claims 12, 13, 17 and 19 of the 964 Patent; and claims 1 to 7, 9, 11, 12, 18 to 21, 23, 24, 26, 27, 31 to 32, 36 to 38, 40 to 45, 47, 49, 50, 56 to 59, 61, 62, 64, 65, 69 to 70, 74 to 76, and 78 to 80 of the 807 Patent.

7. The matter be remitted to the primary judge for the hearing and determination of the remaining questions of infringement of the 807 Patent.

8. The First Respondent pay the Appellants' costs of and incidental to the appeal and the their costs incurred to date in the proceeding below subject to any costs orders made by the primary judge before the trial.

9. Such further or other order or declaration as the Court sees fit.

Appellants' address

The Appellants' address for service is:

MinterEllison
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Melbourne VIC 3000

Attention: Shyama Jayaswal

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The First Appellant's address is 299 Lane Cove Road, Macquarie Park NSW 2113.

Service on the Respondents

It is intended to serve this application on all Respondents.

Date: 12 February 2019

Signed by Shyama Jayaswal
MinterEllison
Lawyer for the Appellants

Schedule

No. of 2019

Federal Court of Australia

District Registry: New South Wales

Division: General

Appellants

Second Appellant: BGP Products Operations GmBH

Respondents

Second Respondent: Alkermes Pharma Ireland Limited

Date: