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Case No: HP-2015-000007
HC-2014-001795
HP-2014-000021
HP-2015-000049
HP-2020-000034

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

Rolls Building
7 Rolls Building
London EC4A 1NL

Date: 18/07/2022

Before :

MR JUSTICE ZACAROLI

Between :

- (1) DR REDDY'S LABORATORIES (UK)
LIMITED
- (2) SECRETARY OF STATE FOR HEALTH AND
SOCIAL CARE
- (3) THE NHS COMMISSIONING BOARD
(OPERATING AS NHS ENGLAND)
- (4) THE WELSH MINISTERS
- (5) THE DEPARTMENT OF HEALTH IN
NORTHERN IRELAND
- (6) THE REGIONAL HEALTH AND SOCIAL
CARE BOARD (OPERATING AS
THE HEALTH AND SOCIAL CARE BOARD)
- (7) THE SCOTTISH MINISTERS
- (8-21) SCOTTISH HEALTH BOARDS
- and -
- WARNER-LAMBERT COMPANY LLC

Inquiry
Claimants

Inquiry
Defendant

Christopher Hall (instructed by **Mishcon de Reya LLP**) for the **First Inquiry Claimant**
Brendan McGurk and Alice Hart (instructed by **The Government Legal Department**) for
the **Second to Fifth Inquiry Defendants**
Daniel Selmi (instructed by **RPC**) for the **Seventh to Twenty-first Inquiry Claimants**
Richard Boulton QC, Tim Austen and Thomas Lunt (instructed by **Kirkland & Ellis**
international LLP) for the **Inquiry Defendant**

Hearing dates: 5 and 6 July 2022

Approved Judgment

This judgment was handed down remotely by circulation to the parties' representatives by email and released to the National Archives. The date and time for hand-down is deemed to be 10am on Monday 18 July 2022.

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Mr Justice Zacaroli:

1. The background to these inquiry claims is set out in a judgment on certain preliminary issues handed down on 30 July 2021 ([2021] EWHC 2182 (Ch)). I will adopt the same abbreviations as used there.
2. It is common ground that each of the parties will be disclosing confidential documents, and that some form of protection of that confidentiality is required.
3. Paragraph 50 of a case management order of Birss J dated 18 December 2020 (the “Birss J Order”) provided for the parties to agree as soon as practicable upon a common confidentiality ring for the purposes of disclosure.
4. The Birss J Order contemplated that the confidentiality ring would comprise both a basic tier, for ordinary confidential information, (the “Basic Tier”) and an “attorney eyes only” tier. It contemplated that admittance to the Basic Tier would be restricted (in relation to each party) to external legal advisors and experts, at least one in-house counsel and at least one additional nominated employee who is capable of giving instructions, and that each expert, in-house counsel and nominated employee would provide written undertakings, in a form to be agreed. The order also contemplated that admittance to the attorney eyes only tier would be restricted to external legal advisors and experts only. While the name is inaccurate because experts, and not merely attorneys, are within this tier, I will nevertheless refer to it by the short-hand adopted by the parties: the “AEO Tier”.
5. The parties that remain (many others having settled in the intervening 18 months) have yet to agree the terms of the confidentiality ring. At a disclosure case management conference held on 5 and 6 July 2022 the points that remained in issue for determination were as follows:
 - (1) Whether disclosure of “merely confidential” material (i.e. that which would be disclosed within the Basic Tier) should be given on terms requiring counsel and solicitors to be named and give signed undertakings as to confidentiality;
 - (2) In relation to certain categories of information, namely (1) documents relating to a medicine margin scheme operated by NHS EWNI, or an equivalent scheme operated by NHS Scotland (“MMS Documents”); and (2) documents relating to a Pharmaceutical Price Regulation Scheme or a subsequent, re-named scheme that performs a similar function (“PPRS Documents”), whether:
 - (1) the disclosure should be excluded from Dr Reddy’s action;
 - (2) counsel and solicitors should be named and required to give signed undertakings as to confidentiality;
 - (3) counsel, solicitors and experts should be required to give signed undertakings excluding them from having any involvement (including by way of advising any client or other person in relation to) the preparation of any pricing strategy for any pharmaceutical company for the period of 3 years after either that person is removed from the confidentiality ring or the proceedings are concluded (“PSU Undertakings”);

(4) the disclosure should be restricted to the AEO Tier.

The principles

6. The principles to be applied in considering how to protect confidential information, with particular reference to patent cases, were helpfully drawn together by Floyd LJ in *Oneplus Technology (Shenzen) Co Ltd v Mitsubishi Electric Corporation* [2020] EWCA Civ 1562, at §39 (with references to the authorities removed):

“i) In managing the disclosure of highly confidential information in intellectual property litigation, the court must balance the interests of the receiving party in having the fullest possible access to relevant documents against the interests of the disclosing party, or third parties, in the preservation of their confidential commercial and technical information.

ii) An arrangement under which an officer or employee of the receiving party gains no access at all to documents of importance at trial will be exceptionally rare, if indeed it can happen at all.

iii) There is no universal form of order suitable for use in every case, or even at every stage of the same case.

iv) The court must be alert to the fact that restricting disclosure to external eyes only at any stage is exceptional.

v) If an external eyes only tier is created for initial disclosure, the court should remember that the onus remains on the disclosing party throughout to justify that designation for the documents so designated.

vi) Different types of information may require different degrees of protection, according to their value and potential for misuse. The protection to be afforded to a secret process may be greater than the protection to be afforded to commercial licences where the potential for misuse is less obvious.

vii) Difficulties of policing misuse are also relevant.

viii) The extent to which a party may be expected to contribute to the case based on a document is relevant.

ix) The role which the documents will play in the action is also a material consideration.

x) The structure and organisation of the receiving party is a factor which feeds into the way the confidential information has to be handled.

7. I was referred to the form of order that was in fact made in the *Oneplus* case. I note that external solicitors and counsel were *not* required to give the relevant confidentiality undertakings (although expert witnesses were required to do so).

The confidentiality of the MMS Documents and the PPRS Documents

8. In very broad outline, the medicine margin scheme and the PPRS scheme are designed to cap the growth of NHS spending on branded medicines. The PPRS scheme imposes a percentage rebate (akin to a tax) on pharmaceutical companies, while the medicine margin scheme places a cap on the profits of pharmacies, enabling the NHS Parties to claw back profits made in excess of the cap. The schemes are voluntary and depend on the provision of large amounts of data by pharmaceutical companies and pharmacies across the industry, on a confidential basis. According to a witness statement of Helen Horsfall of the Government Legal Department dated 7 January 2022, this data is “highly sensitive”, even where it is now several years old. In a further witness statement of Frederick Groves of the Government Legal Department dated 27 June 2022, the following evidence was given as to the confidentiality of this information:

“Relevant to this point is the following, set out by Mr. McGurk at the March Hearing (pages 91-92 of the transcript): “...we are not just dealing with one third party’s confidential information here; we are dealing with a whole industry’s confidential information on pricing, pricing strategy... there is a risk, my Lord, as I mentioned, of gaming, if you are involved from the perspective of pharmaceutical A, and you understand the pricing strategy of B, C, D, E and F, your competitors, particularly within PPRS, where of course it is worked out on a basis of the basket of the products that you bring to market as a pharmaceutical. There is a risk, of course, of gaming as between different drugs in different markets and we are super-sensitive about that.” ... The information that the Department for Health and Social Care (“DHSC”) hold from other companies is obtained under confidential agreements which stipulate that the information is to only be used for a specified purpose and will be kept confidential. DHSC consider that this confidential agreement still applies irrespective of how old the data may be. For example data provided under PPRS or margin survey may be several years old now but DHSC consider it still has a duty to keep it confidential. If manufacturers and pharmacy contractors see DHSC sharing it, irrespective of the age of the data, they may be reluctant to provide it with the data that it needs to run the current schemes. Furthermore, DHSC believes this still applies even when the data has been aggregated or anonymised. For example data from the margin survey on individual purchases made by pharmacies, may have been aggregated or anonymised but if for example there was only two or three suppliers in the market for a particular presentation, a company could retrofit their competitors selling price and volume. This equally applies to presentation level net and gross sales data provided under PPRS, it gives a competitor an insight into another company’s pricing strategies. On this basis, NHS EWN1 aver that the terms of the CRO are suitable to protect the confidential information and interests of all of the parties.”

9. This evidence was not contradicted by the other parties. Nor was it seriously contested that the confidential nature of such information justified heightened protection afforded by an AEO tier within the confidentiality ring. I accept that it does, and that an AEO tier is justified in respect of it, certainly at this stage. Whether it is appropriate to continue to exclude representatives of the parties themselves from the confidentiality ring at trial is a matter that should be revisited at a later stage.

Dr Reddy's position

10. It was Dr Reddy's position at the hearing that neither the MMS Documents nor the PPRS Documents were relevant to any issue in its inquiry claim. The NHS Parties did not disagree. Pfizer's position was that they could not currently identify any issue in Dr Reddy's inquiry claim to which the documents were relevant, but wished to reserve its position. Accordingly, at the hearing I directed that the MMS Documents and the PPRS Documents would not be provided to Dr Reddy's. It remains open to Pfizer, if it considers in the future that the documents are relevant to Dr Reddy's claim, to apply to amend its defence. Any such application would be treated on its merits at the time it was made.
11. For the moment, therefore, there is no need to consider confidentiality undertakings by any representatives of Dr Reddy's, since in relation to the only material so far identified as falling within the AEO tier, Dr Reddy's will not receive that material at all.
12. It is premature, in my judgment, to reach any conclusion about whether an AEO tier is justified and, if so, on what terms in relation to any other possible category of confidential information. That is because the determination of those questions involves balancing numerous factors including, importantly, the nature and degree of confidentiality in the relevant materials, and no such materials have yet been identified.

The confidentiality undertakings and the PPRS and MMS Documents

13. The dispute between Pfizer and the NHS Parties under this head is whether external lawyers (solicitors and counsel) should be required, before they are permitted access to the PPRS and MMS Documents, to sign written undertakings that they will abide by the court's order. (Dr Reddy's sided with Pfizer on this issue, but the point became moot so far as Dr Reddy's were concerned in view of the conclusion that they would not see the relevant documents.) The form of undertaking sought is in the following terms (as regards the question of confidentiality):

“1. I have carefully read, understand and will comply with all of the paragraphs of the attached Confidentiality Order dated [] 2022 (“Order”) as if I were individually a party thereto.

2. The defined terms used in this Confidentiality Undertaking are as defined in the Order.

3. My obligations pursuant to the Order include but are not limited to the following:

(i) I will comply with the obligations in paragraphs 4.1 to 7.2 to of the Order as if I were a ‘Receiving Party’ for the

purposes of the Order (save that I agree that if I am for any reason removed from the Confidentiality Club I will comply with the provisions of paragraphs 7.1-7.2 of the Order as if the Proceedings had concluded as at the date of my removal);

(ii) If provided with Confidential Materials I will not disclose any Confidential Materials or any information derived from them to anyone not qualified under paragraph 5.1 of the Order;

(iii) If provided with AEO Materials I will not disclose any AEO Materials or any information derived from them to anyone not qualified under paragraph 6.1 of the Order;

(iv) I will not disclose any Materials for any purpose other than the Purpose; and

(v) If I become aware of any breach (or suspected breach) of this Confidentiality Undertaking, including any unintentional or inadvertent disclosure, I shall notify the English solicitors of the Party instructing me in the Proceedings and/or whose representative I am pursuant to paragraph 5.1 of the Order as soon as practicably possible after becoming so aware, giving full details of any such breach.

4. I agree that if I breach this Confidentiality Undertaking, I will be subject to the jurisdiction of the English Court in respect of the breach.

6. This Confidentiality Undertaking shall be governed by English law.

7. The English Courts shall have exclusive jurisdiction to determine any dispute or claim arising from this Confidentiality Undertaking (including non-contractual disputes or claims).”

14. NHS EWNI asked me to take into account that the form of undertaking was first proposed by Pfizer. In fact both Pfizer’s and the NHS Parties’ positions had changed, on certain of the issues now raised for determination, over the course of negotiating the terms of the confidentiality ring. It was not suggested that there was any legal basis for holding either side to a position they had formally taken in negotiations. I have determined the issues that arose on this application on their merits, without regard to the previous positions taken by any party.
15. The principal objection to this form of undertaking being required from solicitors and counsel is that they are already under duties which prevent them from doing anything which is prohibited by the order. Thus, for example, a barrister or solicitor who has knowledge of the court’s order prohibiting any use or dissemination of the confidential information beyond the confidentiality ring, would be under equitable duties, and duties to the court enforceable by proceedings for contempt of court, to abide by the terms of the order. (Dr Reddy’s had advanced another objection, namely that their Leading

Counsel was not prepared to give such undertakings because any liability that might arise under it would not be covered by his professional indemnity insurance. Pfizer did not advance the same objection.)

16. I did not understand Mr McGurk to dispute that proposition. Indeed, in relation to confidential information in the Basic Tier he was prepared to accept that an express acknowledgment by solicitors and counsel that their existing duties precluded them from acting inconsistently with the terms of the proposed undertakings would suffice. Mr Boulton QC (who appeared for Pfizer) said that Pfizer's solicitors and counsel were prepared to provide such acknowledgements.
17. Mr McGurk maintained, however, that in relation to the AEO Tier, NHS EWNI would still require signed confidentiality undertakings. He pointed to the fact that in other cases such undertakings had been given by solicitors and counsel. In particular he referred to five cases in the Technology and Construction Court and one in the Chancery Division, in which confidentiality undertakings had been given by external solicitors and counsel: *R (on the application of the Good Law Project Limited) v Secretary of State for Health and Social Care* (Order of Waksman J dated 23 June 2022); *R (on the application of the Good Law Project Limited) v Minister for the Cabinet Office* (Order of O'Farrell J dated 26 January 2021); *MSI Defence Systems Limited v Secretary of State for Defence* (Order of O'Farrell J dated 14 October 2020); *Mitie Limited v Secretary of State for Justice* (Order of Fraser J dated 17 January 2020); *Leonardo MW Ltd v Secretary of State for Defence* (Order of Coulson J dated 30 November 2016); and *Fijitsu Services Limited v Department for Transport* (Order of Edward Murray sitting as a Deputy Judge of the Chancery Division dated 28 March 2014).
18. In none of those cases, however, does there appear to have been any objection taken, and thus any requirement for the court to make any decision. Moreover, the purpose of the undertaking in most of the cases appears to have been to provide details dealing with such administrative matters as storage, copying and destruction or deletion of confidential documents, matters which are proposed to be dealt with in this case in the body of the confidentiality order.
19. Similarly, as I have noted above, in *Oneplus* express undertakings as to confidentiality were given by most recipients of confidential information, but *not* by external solicitors and counsel. The only case cited to me in which express consideration was given to external lawyers giving such an undertaking was *IPCom GmbH & CO KG v HTC Europe Co Ltd* [2013] EWHC 52 (Pat), where (at §35) Floyd J noted that external lawyers were not being required to give confidentiality undertakings, apart from a Dr Sedlmaier. Although an external lawyer, he worked for a law firm whose principal also ran IPCom. Moreover Dr Sedlmaier had himself been co-ordinating IPCom's strategy since 2007. In fact, when he was proposed for inclusion within the confidentiality ring as a nominated individual, Dr Sedlmaier had indicated he was prepared to provide an undertaking. In the special circumstances of that case, in particular as a result of "...the concerns expressed ... about his closeness to IPCom and his involvement in negotiations outside the context of the action", Floyd J concluded that it was desirable that he should give such an undertaking.
20. It is for the party seeking to impose confidentiality restrictions to justify them. While recognising that the relevant recipients of the information (external solicitors and counsel) are already under obligations which are wholly reflected in the proposed

written undertakings, the NHS Parties consider that undertakings are nevertheless necessary in order to bring home to those recipients the importance of complying with the obligations.

21. In my judgment, those concerns are met in this case (where it is not suggested that there are any special factors, such as those to which I have referred above in *IPCom* so far as Dr Sedlmaier was concerned) by requiring an acknowledgment by external solicitors and counsel included within the AEO Tier that they have read the confidentiality order, and that the obligations contained in the undertaking sought by the NHS Parties are reflected in their existing duties and obligations. That is sufficient to protect the interests of the NHS Parties and the third parties whose confidential information is contained within the MMS and PPRS Documents. It follows that the relevant solicitors and counsel in the AEO Tier will need to be identified.

Confidentiality undertakings and the Basic Tier

22. As I have noted above, the NHS Parties did not press for confidentiality undertakings in relation to information disclosed within the Basic Tier, on the basis that similar acknowledgments were given by the solicitors and counsel receiving such information. I consider that such acknowledgments, which impose no additional burden on any of the solicitors and counsel, are similarly justified here, on the basis that they serve to reinforce the importance of complying with the confidentiality order by each of the persons who is to receive the information.

The PSU Undertakings

23. The dispute here is again between Pfizer and the NHS Parties. Mr McGurk said that the NHS Parties could not provide the MMS and PPRS Documents to external solicitors, counsel and experts unless they were each willing to sign a PSU Undertaking. Mr Boulton said that none of Pfizer's solicitors, counsel or experts would be prepared to sign such an undertaking.
24. The form of the undertaking sought is as follows:-

“I will have no involvement in (including by way of advising any client or other person in relation to) the preparation of any pricing strategy within Warner-Lambert, Viatrix Inc or Dr Reddy's for the period of 3 years after either I am removed from the Confidentiality Club or Proceedings are concluded.”
25. When Mr Boulton pointed out that there was no logical reason for limiting the undertaking to involvement in pricing strategy of the entities that remain in the action, given that the confidential information comprised within the MMS and PPRS Documents related to all pharmaceutical companies who participated in the schemes, Mr McGurk accepted that the undertaking would indeed have to encompass all such entities.
26. No authority was cited to me where a court had been called upon to decide, in the face of objection from a relevant party, whether an undertaking in this form by external advisers and experts was justified.

27. In four of the orders made in cases in the Technology and Construction Court to which Mr McGurk referred me, there was some form of undertaking not to be involved with certain commercial activities (including by way of providing advice) for a period of time after the end of proceedings. In two of them (*R (on the application of the Good Law Project Limited) v Secretary of State for Health and Social Care* (Order of Waksman J dated 23 June 2022); and *MSI Defence Systems Limited v Secretary of State for Defence* (Order of O'Farrell J dated 14 October 2020)) such undertakings were given by employees or customer representatives, but *not* by legal advisors, who gave only confidentiality undertakings. In one of them (*R (on the application of the Good Law Project Limited) v Minister for the Cabinet Office* (Order of O'Farrell J dated 26 January 2021)), such undertakings were given both by employees and by legal advisors. In the fourth case (*Mitie Limited v Secretary of State for Justice* (Order of Fraser J dated 17 January 2020)), a limited form of such undertaking was given by legal advisors, but a broader form given by employees.
28. In this case, so far as external solicitors and counsel are concerned, Mr McGurk made the point that they are likely to be predominantly at least, litigators, so that they are unlikely to be prejudiced by having to give such undertakings. That, however, is the wrong starting point. It is not a justification for making an order against, or requiring undertakings to be given by, a party that they are unlikely to be prejudiced by it. On the contrary, it is for the person seeking to impose a restriction to justify the need for it. The justification here is the risk of use being made of confidential material, even inadvertently, in the course of advising other pharmaceutical companies on pricing strategy. If the persons against whom the restriction is sought to be imposed are unlikely to be in that position, then the risk is lower and the justification for imposing the order commensurately weaker.
29. It is also important to bear in mind that any use of the confidential information in advising any other entity would be a breach of the obligations of confidence which are already owed by solicitors and counsel (as described above). In the case of external solicitors and counsel, their professional experience means that they are well-versed in the need to partition information obtained in different cases, and the restriction on using information acquired confidentially in the context of a particular case in any other circumstances.
30. I have not been shown any case in which a similar restriction has been imposed upon experts, certainly not where it has been ordered following objection and determination of rival arguments.
31. I acknowledge the heightened confidentiality in the materials, and the risks to the NHS Parties and to the public interest if the MMS and PPRS schemes were damaged as a result of lack of confidence of those who provide the information to the NHS. There are, however, a number of factors which militate against imposing the PSU Undertakings.
32. First, the proposed limitation on the freedom of any expert appointed by the other parties to work in an advisory capacity in their field of expertise is extremely wide, since it relates to any pharmaceutical company and over a period of three years after these proceedings have finished (or the expert leaves the confidentiality club).

33. Second, any expert owes duties of confidentiality including the duty not to make any use of the information learned in one case for any other purpose.
34. Third, expert witnesses are likely to be of sufficient experience that they are well used to considering carefully and conscientiously what work they can and cannot take on in light of information acquired by them from other engagements.
35. Fourth, while the information is undoubtedly of a highly confidential nature, and there is nothing to contradict the contention in the NHS Parties' evidence that it retains its confidence even after the passage of time, it is nevertheless already a number of years out of date: the most recent information dates from 2020 and the rest of it goes back a number of years prior to that. I note that the basis for the contention that it remains confidential is that the information was provided under contractual restrictions which the NHS Parties consider continue in force notwithstanding the passage of time. That is not the same as saying that the information retains its inherently confidential nature, such that the risk of prejudice if there is any leakage in the information remains at the same level, notwithstanding the passage of time.
36. Balancing all of these factors, I conclude that the NHS Parties have not demonstrated sufficient justification for requiring the PSU Undertakings to be given before disclosing the MMS and PPRS Documents either to external solicitors and counsel or to experts included within the AEO Tier.

Conclusion

37. In relation to each of the questions that were raised for determination at the hearing, I conclude as follows:
 - (1) The MMS and PPRS Documents will not be provided to Dr Reddy's. They will be provided to Pfizer within an AEO Tier that, at this stage, relates only to those documents.
 - (2) Disclosure of confidential information within the Basic Tier and the AEO Tier relating to the PPRS and MMS Documents will be on the basis that external solicitors and counsel will be required to provide a written acknowledgment that they have read the confidentiality order and that the obligations set out in the form of undertaking proposed by the NHS Parties at this hearing reflect their existing duties.
 - (3) Neither external solicitors, counsel or experts are required to provide PSU Undertakings.