

If this Transcript is to be reported or published, there is a requirement to ensure that no reporting restriction will be breached. This is particularly important in relation to any case involving a sexual offence, where the victim is guaranteed lifetime anonymity (Sexual Offences (Amendment) Act 1992), or where an order has been made in relation to a young person

This Transcript is Crown Copyright. It may not be reproduced in whole or in part other than in accordance with relevant licence or with the express consent of the Authority. All rights are reserved

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURT
OF ENGLAND & WALES
COMMERCIAL COURT (QBD)
[2021] EWHC 1878 (Comm)



No. CL-2020-000375

Rolls Building
Fetter Lane
London, EC4A 1NL

Tuesday, 15 June 2021

Before:

MR JUSTICE ROBIN KNOWLES

B E T W E E N :

ACERUS PHARMACEUTICALS CORPORATION
(incorporated in Canada)

Claimant

- and -

RECIPHARM LIMITED

Defendant

MISS S. ABRAM (instructed by Hogan Lovells International LLP) appeared on behalf of the Claimant.

MR A. HEPPINSTALL QC (instructed by Knights Plc) appeared on behalf of Defendant.

J U D G M E N T

(Via Microsoft TEAMS)

MR JUSTICE ROBIN KNOWLES:

- 1 This is the judgment of the court on the trial of a preliminary issue on the construction of a clause of a commercial contract. The claimant, Acerus, seeks damages from the defendant, Recipharm, for loss of profits and costs caused by Recipharm's alleged failure to perform contractual obligations under a written Manufacturing Agreement dated 12 May 2009, as amended ("the MA").
- 2 Estrace is a plant derived, medicinal product for the treatment of symptoms of the menopause. Acerus is a Canadian pharmaceutical company which holds the rights in Canada to Estrace. The MA was concluded, as it happens, between Acerus' predecessor, Shire Pharmaceuticals Ireland, and Recipharm's predecessor, Recipharm 1.
- 3 Under the MA, Recipharm 1 was appointed to manufacture Estrace. Acerus is the successor to the rights and liabilities of Shire. Recipharm is the successor to the rights and liabilities of Recipharm 1.
- 4 In the event, Recipharm stopped supplying Estrace to Acerus. The circumstances were that the relevant manufacturing licence was suspended. Recipharm gave two years' notice to terminate the MA, but accepts failing to supply Estrace for in excess of two years, although it is denied that that was a breach of contract.
- 5 The denial includes the contention that Acerus' claim for damages is excluded under a clause 9.3 of the MA. Recipharm says that that clause excludes a claim for loss of profits and costs and that is the nature of the claim that Acerus would bring.
- 6 At a case management conference towards the end of last year, Miss Leigh-Ann Mulcahy QC, sitting as a Deputy High Court Judge, directed a trial of a preliminary issue as to the effect of clause 9.3. The issue is framed in the agreed list of issues in these terms,

"What is the proper construction of clause 9.3 of the MA? Does it exclude Recipharm UK's liability to Acerus for damages in respect of additional costs or loss of profits?"
- 7 The preliminary issue ordered originally included a further question in connection with issue 25 on the agreed list of issues, namely, whether, if clause 9.3 has the effect contended for by Recipharm, it is an unfair term under s.3 of the Unfair Contract Terms Act. That contention on the part of Acerus is no longer advanced.
- 8 Within the MA, clause 9 is in the following terms,

"LIABILITY FOR LOSS AND CLAIMS

9.1 Where any Product supplied hereunder is supplied for or is used in clinical trials of medicinal products and for the purpose of or in preparation for any application for regulatory approval then the provisions of this clause shall also apply:

9.1.1 save as set out in this Agreement and for the Technical Agreement Recipharm makes no warranty of whatsoever nature in respect of the services or manufacture of the Product and all other conditions, warranties,

stipulations or other statements as to the Products or defects therein whether express or implied by statute or common law or otherwise howsoever, are hereby excluded to the fullest extent permissible by law;

9.1.2. Shire hereby indemnifies and shall keep indemnified Recipharm and hold it harmless against any and all claims, actions, judgements, damages, lawsuits, costs, expenses or reasonable professional fees brought against suffered or incurred by Recipharm in relation to or arising out of any such clinical trial directly relating to (a) any material breach by Shire; (b) any negligent act or omission of Shire, its employees or agents or (c) the storage, distribution, sale or use of the Product by Shire in any clinical trial, including, without limitation any and all claims against Recipharm for no fault compensation brought on behalf of any patient in any clinical trial provided that the Shire shall not be obliged to indemnify Recipharm where such claims, actions, judgements, damages, lawsuits, costs, expenses or professional fees are attributable to (a) any breach of this Agreement by Recipharm; (b) any act or omission of Recipharm, its employees or agents or; (c) the storage or distribution of any Product by Recipharm;

9.1.3 Shire undertakes to ensure that it has in place insurance with a reputable insurer in an amount sufficient for the purposes of conducting or having conducted any clinical trials including, without limitation, insurance cover for liability to provide no fault compensation as sponsor of a clinical trial and at Recipharm's request Shire shall provide Recipharm with evidence of the existence and maintenance of such cover;

9.1.4 Recipharm shall not, in relation to any such clinical trial be liable to Shire nor any third party for any consequential or indirect loss or damage or loss of profit of whatsoever nature including (but not limited to) damage to goodwill, loss of market share, existing or prospective nor the cost of any delay of any regulatory programme.

9.2 Recipharm shall indemnify Shire, its Affiliates and its and their respective employees, directors, officers, sub-contractors and consultants against legal liability to third parties in respect of all claims, actions, judgements, damages, lawsuits, costs or reasonable expenses or professional fees relating to death and personal injury incurred by Shire in relation to or arising out of breach of contract by Recipharm or any negligent act or omission of Recipharm, or its Affiliates or its or their respective employees, contractors or agents. Any and all liability of Recipharm to Shire, howsoever arising in respect of this Agreement and this performance shall be limited

(except for death and personal injury caused by the negligence or breach of any term of this Agreement by Recipharm or its employees, contractors or agents) to the greater of £2,000,000 or an amount equal to the insurance provided pursuant to clause 9.5.

9.3 In any event and notwithstanding anything contained in this Agreement in no circumstance shall either party be liable to the other in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever to the other, and whatever the cause thereof (i) for any increased costs or expenses, (ii) for any loss of profit, business or contracts, revenues or anticipated savings or (iii) for any special indirect or consequential loss or damage of any nature whatsoever arising from this Agreement or the Technical Agreement.

9.4 As a condition of obtaining an indemnity in the circumstances set out in this clause 9, the party seeking an indemnity shall:

9.4.1 fully and promptly notify the other party of any claim or proceedings, or threatened claim or proceedings;

9.4.2 permit the indemnifying party to take full control of such claim or proceedings;

9.4.3 assist in the investigation and defence of such claim or proceedings;

9.4.4 not compromise or otherwise settle any such claim or proceedings without the prior written consent of the other party, which consent shall not be unreasonably withheld or delayed; and

9.4.5 take all reasonable steps at its expense to mitigate any loss or liability in respect of any such claim or proceedings.

9.5 Each party undertakes to the other to ensure that it has in place product liability insurance with a reputable insurer for at least £1 million for each occurrence or series of related occurrences in any 12 month period for its business and products of the type the subject of this Agreement, and for its obligations under this Agreement. At a party's request ('the requesting party') the other party shall provide the requesting party with evidence of the existence and maintenance of such cover in such reasonable amount as the requesting party may require."

In addition, the MA included the following:

1.2 The headings in this Agreement are for convenience only and shall not affect its interpretation.

...

2.1 Recipharm hereby agrees to act as contract supplier to Shire for the Manufacture of the Products on the terms set out in this Agreement. Recipharm shall at all times upon request by Shire Manufacture the Products for Shire strictly in accordance with this Agreement and the Technical Agreement.

Shire hereby appoints Recipharm as its exclusive supplier for the manufacture of the Products. The exclusivity shall terminate in the event of a material breach, as defined in clause 14, irrespective of whether or not the Agreement is terminated or the material breach is remedied.

....

4.7 In the event that by agreement between the parties Shire agrees to provide any Raw Materials for such Manufacture the following terms shall apply:-

...

...

4.7.6 If any defect in a batch of the Products is the demonstrable and proven result of a defect in any such Raw Materials supplied by Shire then notwithstanding clause 8.2 below Shire shall pay the price for the relevant Products as specified in Schedule 1 together with the cost incurred by Recipharm in correcting or causing to be corrected the defect in accordance with clause 8.2.

...

DEFECTIVE PRODUCTS

...

...

8.2 Subject to clause 8.3, Recipharm shall promptly either correct or cause to be corrected any defect or deficiency notified by Shire pursuant to clause 8.1 and accepted by Recipharm or determined as aforesaid by such independent laboratory. If the defect or deficiency cannot be corrected Recipharm shall as soon as is reasonably practicable supply to Shire appropriate new quantities of relevant Products to replace in full the defective Products concerned and then (if the defective lot or batch has been returned to Recipharm) on Shire's request Recipharm shall promptly destroy the defective batch or lot of the Products or return it to Shire for destruction. In any event any action taken by Recipharm pursuant to this clause 8.2 shall (subject always to clause 8.3) be at Recipharm's sole expense (including re-imburement to Shire of the cost to Shire of any additional materials required by Recipharm and supplied by or on behalf of Shire for the purposes of this clause 8) and subject to clause 8.3 Recipharm shall re-imbure Shire on demand for any costs incurred by Shire in dealing with any such defect or destruction PROVIDED ALWAYS that upon correction of the defect or deficiency or replacement of the defective Products concerned Shire

shall be liable to pay for the corrected Products or the replacement Products (as the case may be) in accordance with 7.7.

8.3 If any defect or deficiency in a batch or lot of the Products is the demonstrable and proven result of a deficiency in any Raw Materials supplied to Recipharm by Shire under clause 4.6 Shire will pay the price specified in Schedule 1 for the relevant nits of the defective Products produced and the costs of correcting or causing to be corrected the deficiency.”

9 Understandably, both counsel referred to the language of Lord Clarke in *Rainy Sky v. Kookmin* [2011] 1WLR 2900 para.21 in these terms,

“The language used by the parties will often have more than one potential meaning ... the exercise of construction is essentially one unitary exercise in which the court must consider the language used and ascertain what a reasonable person, that is a person who has all the background knowledge which would reasonably have been available to the parties in the situation in which they were at the time of the contract, would have understood the parties to have meant. In doing so, the court must have regard to all the relevant surrounding circumstances. If there are two possible constructions, the court is entitled to prefer the construction which is consistent with business common sense and to reject the other.”

10 In argument that was marked by its clarity and concision, Miss Sarah Abram for Acerus urges that, if clause 9.3 was to have the interpretation argued by Recipharm, it would (the present case is an example) allow the supplier, Recipharm, to choose to walk away from its obligations to supply in the period before termination rather than to perform those obligations. In that situation, the only relevant sanction would be a liability for loss of profits, but, on Recipharm’s argument, that liability is taken away by clause 9.3. That scenario of an effective freedom to walk away is not consistent, urges Miss Abram, with business common sense.

11 There is provision to terminate, but one must consider that in the commercial context of supply of product of this character, which would take an appreciable time to replace in terms of supply chain. Miss Abram points out that clause 9.3 is found within clause 9 as a whole. If it was to have the wide effects for which Recipharm contends, it is, as she puts it, “in the wrong place”. That is because clause 9 is all about third-party claims that have consequences for Acerus and Recipharm as between each other.

12 Miss Abram urges that Recipharm’s interpretation, moreover, is inconsistent with other clauses which do allow costs in certain circumstances of failure to perform: clauses 4.7.6 and 8.2 and 8.3 are identified.

13 As for the introductory wording of clause 9.3, Miss Abram contends that the words “in any event” link clause 9.3 to 9.2, which, again, is dealing with the consequences of third-party claims in this industry for one or other of the parties.

14 In support of its contention as to the meaning and effect of clause 9.3, in clear and concise submissions for Recipharm, Mr Adam Heppinstall QC argues that the wording of clause 9.3 is clear. It is not wording that bears alternative meanings. The ordinary meaning of the

words found within clause 9.3 makes, in his submissions, sense if those words are given general application. He acknowledges that clause 9.3 is - what he termed in the course of oral argument - “an island in a sea of clauses that appear to be about indemnities”, but contends that there is nothing wrong with that. He challenges the efforts by Miss Abram to blend clause 9.3 into clause 9.2 so as to make a form of clause 9.2.2. In the course of that challenge, he shows that the compass of clause 9.2 is not coextensive with clause 9.3.

- 15 In written argument, Mr Heppinstall develops the point that the mutual exclusion of unlimited claims for loss of profit is rational and normal. The parties may be concerned at their inability accurately to predict the success of a product or the quantum of each other’s profits. It is open to parties to agree to exclude each other’s claim for profits and that, he contends, is what they have done in the present case. If that is the situation, then the “walk-away” point developed by Miss Abram is not applicable.
- 16 The responses given by Miss Abram to the argument of Recipharm advanced by Mr Heppinstall include the point that the general law would provide some limit to the ability to recover unusual loss of profit.
- 17 The argument of Mr Heppinstall in response to that of Miss Abram, when she refers to other clauses of the contract enabling cost recovery, includes the point that clause 9.3 directs itself to what are termed “increased costs” rather than simply “costs”, but against that Miss Abram is able to point out that the clauses appear to deal with practical reimbursement of costs rather than some type of costs that bear a meaning that can be separated as between “costs” and “increased costs”.
- 18 Be that as it may, and with the benefit of the arguments that were presented on each side, it falls to me to examine the clause and examine it in the way that well-known authority requires, including the passage from *Rainy Sky* to which I have made reference.
- 19 I accept that the language of clause 9.3 is plain, but so, too, is the context of clause 9.3 and, in particular, the fact that it is within clause 9. Clause 9, examined as a whole, is directed to the circumstances that the parties may face when there is a claim by a third party brought against one or other of them. Unsurprisingly, the clause overall deals with the concepts of indemnification and the related requirements on the parties in relation to insurance, including, in particular, insurance where clinical trials are to be undertaken, and product liability insurance. The language of clause 9.3, which, as I have indicated, is plain, is also general in its terms, but, once again, that general character must be considered in the context in which those general terms are used.
- 20 I did not find myself persuaded that clause 9.3 dovetails as a form of extension to clause 9.2, alone, but, as I have emphasised, the important point is that 9.3 sits within clause 9 overall.
- 21 It is, in my judgment, in the unitary exercise that the court is charged to undertake, legitimate to look at the consequences for a particular construction. There are, in the present case, two ways of examining the language of clause 9.3. One is reading it alone, as if it was a freestanding clause, regardless of the fact of its positioning in clause 9, and the other is of reading it in the context of its positioning in clause 9.
- 22 Examining the consequences of treating the clause as though it was freestanding does produce the remarkable - in commercial terms - outcome that Miss Abram identifies in her contention that that cannot be the meaning that was, objectively, the intention of the parties. Examining the consequences of the language in the context of clause 9, however, produces

an entirely sensible result. That examination of consequences is not in any sense conclusive, but it is legitimately part of the unitary exercise.

- 23 The clause does contain in its wide language the words “and whatever the cause thereof”, but even that language takes one back to the essential point here: does one look at that in the context of where the clause is to be found or does one look at that language as though it was in a freestanding location of its own which is not the case?
- 24 The contract in the present case, and in particular the terms that have been included at clause 9 and elsewhere, are very much a one-off. The drafting is open to some forensic criticism and it is not surprising to find that it has produced an argument between the parties, but, with the benefit of the debate on the meaning of the clause, I have reached the clear conclusion that the clause does not have the meaning contended by Recipharm or, more specifically, does not have the application for which Recipharm contends. That clause does not have application to the situation, which is the subject matter of this litigation, and I will make whatever declaration is appropriate to resolve the issue in that way.
- 25 I am grateful for the submissions that have been made. In the course of those submissions, reference was made to other authority, including in particular, the authorities of *Kudos Catering (UK) Ltd v. Manchester Central Convention Complex* [2013] 2 Ll Rep 270 and *Motortrak v. FCA Australia Pty Ltd* [2018] EWHC 990 (Comm.) and authorities referred to in those decisions. Those decisions turned on the particular clause in question in each case and, most importantly, the particular context in which the clause was found. Provided those points - that is that it was the particular clause and its context that was involved in each case - are borne in mind, I do not find the outcomes in those decisions inconsistent in any degree with the outcome that I reach today in the present case.
-

CERTIFICATE

Opus 2 International Limited hereby certifies that the above is an accurate and complete record of the Judgment or part thereof.

*Transcribed by **Opus 2 International Limited**
Official Court Reporters and Audio Transcribers
5 New Street Square, London, EC4A 3BF
Tel: 020 7831 5627 Fax: 020 7831 7737
civil@opus2.digital*

This transcript has been approved by the Judge.