Dealing with liability issues in biotechnology contracts

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Abstract Limitation of liability by a supplier in a commercial biotechnology agreement is a touchy subject; the buyer will not like it, and the English courts may not enforce it. This paper sets out the principles built up by the courts with regard to exemption clauses and suggests some practical steps designed to avoid some of the pitfalls that many contracting parties encounter when dealing with these issues.

Keywords: liability, limitation, exemption, contract

Introduction

One of the toughest nuts to crack in negotiating most commercial biotechnology agreements is the issue of limitation of liability. Usually a supplier of services or products such as research and development work or the contract manufacture of compounds will wish to set a clear and finite limit on the amount the buyer can claim if the supplier fails to fulfil its obligations. No supplier would wish to be faced with a claim from its buyer relating not only to a refund of the price paid but also to other losses, for example loss of profits, which the buyer claims it has incurred as a result of the supplier's failure, the amount of which the supplier cannot control.

The buyer may not be impressed if the supplier seeks to limit its liability in this way, but generally a limitation of liability is a commercial necessity; your insurance cover is capped, so why not your liability? Too many contracts in the biotechnology industry fail to deal with this issue adequately or at all. But even if they are included, will such clauses be effective to let a party off the hook if things go wrong? This paper will review the position of English law on the question of limitation and exclusion clauses in such contracts (particularly in the light of a recent Court of Appeal decision) and will also deal with some practical steps aimed at avoiding difficulties that might otherwise arise.

Liability for what?

Liability in law can arise in a number of ways in connection with a contract. Primarily of course there is liability in breach of contract if one party fails to fulfil its obligations under the contract. In addition there may be separate liability under the law of tort, in particular in negligence. This is a liability that exists independently of the terms of the contract, so that even if a party cannot for some reason successfully claim under the contract itself it may nonetheless sue for the other party's negligence in carrying out its contractual obligations. However, both contractual and tortious liability may be excluded or limited in the contract itself, subject to the various issues dealt with below.

In addition to the express contractual

terms contained in an agreement, there may also be terms implied in the contract by English law. There are a number of circumstances in which the courts will feel entitled to include terms in a contract that are not expressly stated in the document itself, and of particular relevance to the types of biotechnology agreements mentioned above are terms that will be implied by the Supply of Goods and Services Act 1982, especially the implied term that a supplier will carry out a service with 'reasonable care and skill'.[1] Other terms may be implied from the general usage or custom of any particular trade or practice,[2] so that, for example, if a compound used as a raw material in a manufacturing process is usually supplied in batches of a particular quantity then, even if the parties to a contract have forgotten to specify the batch quantities in writing, it might be open to a party to argue that what was intended were those batch quantities that are 'normal' in the industry or from a previous course of dealing between the parties.

It is far better of course from a practical point of view to clearly state all of the contractual obligations that each of the parties is to undertake. There should be precise analytical and other specifications for raw materials, semi-finished products and finished products, with precise quantities and packaging details where relevant. Where a service is to be provided (for example pure research without the manufacture of prototype or finished products), then a clear service protocol should be set out and annexed to the agreement to specify the precise obligations of each party.

If this is done then arguably it will be appropriate to include in the contract a clause excluding all implied contractual terms to the extent permissible at law. This is designed to give certainty that the contractual obligations expressly contained in the agreement are the only contractual obligations undertaken by the parties, and that there are no further obligations which one party could claim at a later date should be implied into the contract.

Can you exclude or limit liability?

Any exclusion or limitation of liability (referred to here as an 'exemption clause') will be looked at with a very jaundiced eye by the court. Since Victorian times the English courts have usually done what they can to remove the effectiveness of exemption clauses despite the fact that they had previously been agreed between the parties. For an exemption clause to be effective at all it must be expressed clearly and without ambiguity,[3] and the party seeking to rely upon an exemption clause must prove that the clause applies to the particular circumstances in question.[4]

In addition, the courts will insist that an exemption clause that it regards as particularly onerous or unusual be fairly brought to the attention of the other party by the party seeking to enforce it.[5] This is why on occasions you may see exemption clauses printed in capital letters in contracts.

The Unfair Contract Terms Act 1977 (UCTA) imposed further fetters on the freedom of parties to limit or exclude their liabilities in contracts. Firstly, under Section 2 of UCTA, it is unlawful to exclude or restrict one's liability for death or personal injury resulting from negligence. This wide-ranging provision has, of course, particular impact in the therapeutics area of biotechnology, and where there is risk that death or personal injury may arise from activities under a contract if they are carried out negligently then the only recourse is to insurance cover; subject to the text below, a contractual term will not be effective here.

A possible method of reducing the area of risk in such circumstances might be for a contractor to insist that its contractual obligations are limited to producing a compound to the precise specifications required by the buyer. If the use by the buyer or others further down the supply chain proves to cause death or personal injury then this is an issue for the buyer, and the buyer might be persuaded to accept a clause in the contract indemnifying the contractor against any liabilities that the contractor might otherwise face with regard to such matters. However, if it could be

shown that the contractor reasonably knew that the compounds could cause death or personal injury then arguably (notwithstanding the fact that the contactor has stuck rigidly to the specifications for the compounds) it probably nonetheless acted negligently in failing to use its knowledge of the relevant scientific area and forewarn the buyer of the possible consequences. The courts have shown that in such circumstances they will need considerable persuasion to permit such an indemnity clause to act effectively in the contractor's favour,[6] but it would seem that a clearly drafted indemnity clause will be effective even where the contractor is negligent and this causes the death of or personal injury to a third party, since nothing in Section 2 of UCTA affects a term of a contract by which one party requires the other (who does not deal as a consumer) to indemnify him against his own liability in negligence to third parties.[7]

Further restrictions on the effectiveness of exemption clauses are imposed by Section 3 of UCTA where a party who seeks to benefit from such a clause has contracted on its written standard terms of business. What precisely are a party's 'written standard terms of business' has come in for some discussion in the courts in recent years. Clearly where a party uses its standard form contract without amendment then Section 3 will be applicable, but the courts have also held that even where the terms of a contract have been carefully negotiated at some length between the parties, the use of an individual standard exemption clause inserted into such a negotiated agreement will render the agreement as being on 'written standard terms of business' so that Section 3 will apply to that exemption clause.[8] This somewhat generous view by the courts of the applicability of Section 3 of UCTA reflects the continued, somewhat jaundiced, approach of English law to exemption clauses in general.

Where Section 3 applies, the party on whose written standard terms of business the contract is based cannot use an exemption clause to exclude or restrict any liability for breach of contract or claim to be entitled (i) to render a contractual performance substantially different from that which was reasonably expected of him or her or (ii) in respect of the whole or any part of his or her contractual obligation, to render no performance at all, unless (in either case) the exemption clause satisfies the requirement of 'reasonableness'.

In addition, where goods are passing from one party to another as part of the contract services, such as in a prototype or manufacturing scenario, Section 7(3) of UCTA states that liability for breach of implied terms relating to the goods' correspondence with description or sample, or their quality or fitness for any particular purpose, cannot be excluded or restricted unless the relevant clause satisfies the requirement of 'reasonableness'.

What is it reasonable to exclude or limit?

'Reasonableness' is defined in Section 11 of UCTA so that the contractual term in question must have been a fair and reasonable one to be included having regard to the circumstances which were, or ought reasonably to have been, known to or in the contemplation of the parties when the contract was made. There are further guidelines on the application of the reasonableness test contained in Schedule 2 of UCTA, and although the Act states that these guidelines are expressly applicable only to Sections 6 and 7 of UCTA,[9] these guidelines have, in practice, been used by the courts also when dealing with Section 3.[10]

Issues to be considered under Schedule 2 of UCTA include the relative strengths of the bargaining positions of the parties, whether the customer received an inducement to agree to the exemption clause or had the opportunity of entering into a similar contract without such a clause with someone else, and, of particular importance in the context of contract manufacture, whether the goods were manufactured, processed or adapted to the special order of the customer. A further

element to the guidelines applicable where an exemption clause limits a party's liability to a specified sum of money is the availability of insurance coverage to that party.[11] As a result, if the party enjoys in practice fairly substantial insurance cover but in its standard written terms has limited its liability to a sum considerably less than that cover, then the courts are highly likely to regard the limitation as being unreasonable and therefore unenforceable.[12]

The relative vagueness of the guidelines on the reasonableness test give the courts in practice considerable latitude when dealing with the validity of exemption clauses, and certainly in recent years the traditionally jaundiced view of such clauses has remained to the fore.

In *Overseas Medical Supplies Limited v Orient Transport Services Limited*[13] a supplier of medical equipment sued a carrier for failing to deliver equipment. A clause in the contract sought to impose specified limits of liability in favour of the carrier, but it was held that the restriction, when viewed in the light of the guidelines mentioned above, was not reasonable and could not be relied upon by the carrier.

In *Horace Holman Group Limited v Sherwood International Limited* (2000),[14] the supplier (here, of an IT system) was held to be in a far better position to obtain insurance against defective performance than the buyer, and further the buyer would have had difficulty in obtaining alternative software on better terms or at all. These factors outweighed the fact that the buyer had entered into the contract and its exemption clauses 'with its eyes open'.

Types of loss

A basic tenet of English contract law is that the successful claimant in a breach of contract action is entitled to an amount in damages that would put him or her in the position he or she would have been in had the contract been properly fulfilled, being recompense for both the losses that resulted 'directly and naturally from the breach' (often referred to as 'direct losses') and also losses of a type that were or ought reasonably to have been contemplated by the parties when they made the contract as being likely to result from such a breach (often referred to as 'consequential losses').[15] Perhaps the most obvious type of what may be thought of as 'consequential loss' is loss of profit.

A frequently encountered type of exemption clause is one that seeks to exclude 'indirect' or 'consequential' losses. However, even if such clauses survive the reasonableness test under UCTA, the courts will be very reluctant to give such clauses any real effectiveness unless they are extremely carefully and clearly drafted. In *Pegler Limited v Wang (UK) Limited*,[16] Wang's limitation clause stated that it would not be liable 'for any indirect, special or consequential loss, howsoever arising including ... loss of anticipated profits ... in connection with or arising out of the supply, functioning or use of [the goods and services supplied]'. However, the court held[17] that Pegler's loss of UK sales amounting from the failure to deliver the contracted IT systems (which amounted to £12.5m) could be claimed since these were 'direct' losses rather than the 'indirect, special or consequential losses' that the clause sought to exclude. The clause might have been valid, but was irrelevant because it did not apply to the type of loss in issue. As a result terms such as 'direct', 'indirect' and 'consequential' losses in contracts should be treated with the utmost caution.

Relief for suppliers?

In the light of the above the position tends to look poor for suppliers who wish to limit their liability, but in a recent case[18] the Court of Appeal looked again at the effectiveness of a clause that sought (i) to exclude all liability for 'indirect or consequential losses' and (ii) to cap any liability that the supplier did incur to the contract price (in other words the disappointed buyer might be entitled to a refund but nothing more).

In line with the traditional approach of the courts outlined above, the first instance judge had held that these provisions were

'unreasonable in their entirety' and had given judgment for the buyer, but the Court of Appeal took note of a special addendum that had been negotiated by the parties to what was otherwise the supplier's standard exemption clause which required the supplier, in addition to that clause, to 'commit to [its] best endeavours in allocating appropriate resources to the project to minimise any losses that may arise from the Contract.' The trial judge had regarded this last-minute amendment as 'virtually meaningless', but in contrast Chadwick LJ (who gave the Court of Appeal's leading judgment) felt that its inclusion was significant, and meant that unless the supplier did use its best endeavours to allocate appropriate resources to ensure that the relevant products performed in accordance with the relevant specification then it would not be able to rely on the exemption clause to exclude liability for indirect and consequential losses. As a result, the exemption clause was to be read in a far narrower way than the earlier judge had supposed.

The next question was whether each of the two elements of the clause, read in this restrictive way, was fair and reasonable. Chadwick LJ noted that the buyer included exemption clauses in its standard agreements with its own customers that were of a similar type to the exemptions found in the supplier's contract. As a result, the buyer clearly knew full well the nature and intended effect of such a clause. The parties were of equal bargaining strength. On the other hand, the buyer could probably not have found similar software on better terms.

Chadwick LJ then looked at the question of insurance; not, as indicated in Section 11 of UCTA, in the context of an exemption clause that limits a party's liability to a specified sum of money (the second part of the supplier's exemption clause),[19] but rather with regard to indirect or consequential losses (the first part of the clause).[20] There was particular risk that customised software (as here[21]) might not work as intended, and that therefore the customer would suffer a loss of profits. Both sides recognised, or ought to have recognised, this risk, but whereas the supplier was in a better position to assess (and therefore insure against) the chance that the software would not work correctly, the buyer was in a better position to assess the amount of the potential loss it would suffer if the software failed to perform properly. As a result, it was right that a contract contain a provision stating who was to bear the risk of indirect losses, a provision that would no doubt be negotiated along with the overall price. The part of the exemption clause dealing with indirect losses was reasonable.

With regard to the second part of the exemption clause, Chadwick LJ looked at the Sale of Goods Act which states that in the case of a breach of warranty of quality the measure of damages is *prima facie* (ie not including any indirect losses that the buyer might prove in addition) the difference between the value of the goods at the time of delivery to the buyer and the value they would have had if they had fulfilled the warranty.[22] The second part of the exemption clause was intended to restrict the liability for losses arising directly from a breach of contract to the price paid. A limitation of liability for direct loss to the price paid for the goods was merely a substitute, agreed by the parties, for the approach suggested by the Sale of Goods Act noted above, and was also reasonable.

Where does this leave the supplier of biotechnological goods or services? In words that will no doubt be used many times by counsel in future cases, Chadwick LJ said

> Where experienced businessmen representing substantial companies of equal bargaining power negotiate an agreement, they may be taken to have had regard to the matters known to them. They should, in my view, be taken to be the best judge of the commercial fairness of the agreement which they have made; including the fairness of each of the terms of that agreement. They should be taken to be the best judge on the question whether the terms of the agreement are reasonable . . . Unless satisfied that one party has, in effect,

> taken unfair advantage of the other – or that a term is so unreasonable that it cannot properly have been understood or considered – the court should not interfere.

Is this freedom at last for the supplier community to limits its liability almost at will? On the facts of the case, the court found it necessary to go to some lengths to read the relevant provisions of the contract in a very narrow way before it felt in a position where it could declare them 'reasonable'. The view of indirect or consequential losses appears to be at odds with the British Sugar[17] and Pegler[16] cases – Chadwick LJ seems to assume that lost profits are consequential losses, whereas we have seen that this is not necessarily the case. I must confess some sympathy for the earlier judge's view that the addendum was 'virtually meaningless', and it is remarkable that Chadwick LJ was able to extract from it a meaning that so impacted on the effectiveness of the exclusion of indirect losses. If this analysis is correct, why does the addendum not also jeopardise the second sentence of the exemption, the limitation to the price paid?

As a result I suspect that this decision will be something of a mixed blessing for the supplier industry. The supplier won its appeal, and there are some robust words from the court about freedom of contract, but it may be that the exemption clause here was only reasonable because it will not work (in part at least) unless the supplier can show that it has complied with the requirements of a rather unusual addendum. The court has clearly retained the traditional reluctance of English law to accept at face value clauses of this nature, and there remains considerable scope for courts in the future to find against suppliers on such issues. Just how much light this decision sheds on this area of law is open to debate.

Practical steps

As indicated above, since much of the current law is based on the historically rather jaundiced view of the courts of exemption clauses in general and on the vagueness, in practice, of the 'reasonableness test' under UCTA, clearly defined obligations should be set out in or annexed to the contract to ensure, as far as possible, that both parties know where they stand in terms of what is expected of them under the agreement. From a supplier's point of view, the buyer should be required to be as specific as possible in its requirements, and ideally to undertake responsibility for whether the specifications annexed to the contract meet its overall requirements.[23] This position may be bolstered even more from the supplier's point of view if there is an express obligation on the buyer to actually select the raw materials that the supplier is to use in its research or manufacturing activities. The supplier will wish to see an exclusion of all obligations not expressly set out in the agreement.

If in a manufacturing scenario products are to be produced in batches then there should be a batch test system clearly set out, ideally undertaken by the buyer, which will then put an onus on the buyer to identify any defects in products and report these immediately to the supplier. Liability in such circumstances might effectively be reduced to the cost of shipping the defective products back to the supplier and the manufacture of replacement products, this avoiding any suggestion that liabilities arising from further down the supply chain might find their way to the supplier's door.

Conclusion

In conclusion, it can be said that contractual exemption clauses are extremely useful in trying to identify the areas and the amounts of liability that a party will accept and such clauses should be present in any properly negotiated agreement. However, such clauses need to be extremely carefully drafted with an eye to the particular circumstances that may arise under the contract in question, and cognisance should also be taken of the fact that, however well drafted such clauses may be, they are likely to come under the severest of scrutiny by the courts if they are ever challenged.

Reliance should therefore not be placed on contractual exemption clauses alone; the proper setting out of clear contractual obligations and the obtaining of appropriate insurance cover must also be addressed.

References

1. Section 13 Supply of Goods and Services Act 1982.
2. *Hutton v Warren* (1836) 1 M & W 466.
3. *Ailsa Craig Fishing Co Limited v Malvern Fishing Co Limited* [1983] 1WLR964; *Photo Production Ltd v Securicor Transport Ltd* [1980] A.C 827.
4. The so-called contra proferentem rule – *Pera Shipping Corporation v Petroship SA* [1984] to Lloyds rep.363.
5. *Thornton v Shoe Lane Parking Limited* [1971] 2QB163.
6. *Walters v (1) Whessoe Limited and (2) Shell Refining Co Limited* [1968] 1WLR1056.
7. *Thompson v Lohan (Plant Hire) Limited* [1987] 1 WLR 649.
8. *St Albans City Council v International Computers Limited* [1995] FSR 686. In *South West Water Services Limited v International Computers Limited* (1999) BLR 420, although South West Water had initially offered its own limitation clauses, these were rejected by ICL and the limitation clauses were taken from a ICL systems supply agreement. The court held that even though the resultant contract contained extracts from the standard terms and conditions of both parties, and the parties had negotiated extensively, this did not assist ICL as the exemption clauses had been taken from ICL's standard terms and had not been effectively amended. A similar approach was taken by the court in the Pegler case (see note 16 below) – the exemption clauses were inserted and were regarded by Wang as effectively non-negotiable, and hence this part of the contract was held to be on Wang's standard terms.
9. Section 11(2) UCTA. Section 6 implies terms into sale of goods and hire purchase contracts regarding ownership of goods, the accuracy of any description of goods and their quality or fitness for a particular purpose. In addition both Sections 6 and 7 give special rights to consumers which are not relevant to this paper.
10. *Salvage Association v Cap Financial Services Ltd* [1995] FSR 654.
11. Section 11(4) UCTA states that where a party seeks to restrict liability to a specified sum of money, the reasonableness of that limitation shall be viewed by the court in the light of the resources available to the party seeking to limit his liability, and in particular how far it was open to him to cover himself by insurance.
12. *St Albans City Council v International Computers Limited* [1995] FSR 686.
13. (1999) CLC 1243.
14. LTL 27/7/2000.
15. *Hadley v Baxendale* (1854) 9 Exch 341.
16. (2000) BLR 218.
17. Following the Court of Appeal decision in *British Sugar plc v (1) NEI Power Projects Limited (2) GEC Alsthom Distribution Switchgear Limited* (1998) IT&CLR 125.
18. *Watford Electronics Limited v Sanderson CFL Limited* [2001] All ER (D) 290 (Feb).
19. The provision in Section 11(4) referred to in note 11 above.
20. Chadwick LJ thought that the insurance position should be included in the circumstances that were, or ought reasonably to have been, known to or in the contemplation of the parties when the contract was made for the purposes of Section 11(1) UCTA. Hence it appears not to be an aspect that is relevant solely to clauses imposing a set financial limit of liability, as might be suggested by Section 11(4).
21. There seems to be no reason to doubt that the principle applied here to customised software should also apply to bespoke R&D or contract manufacture work.
22. Sale of Goods Act 1979 Section 53(3).
23. In *Anglo Group plc v Winther Brown and Co Limited and others* (2000) IT&CLR 559 the buyer was required to accept responsibility for the selection of the computer system under the contract, and there was nothing to show that the buyer had relied on the skill or judgment of the supplier. Accordingly, the buyer could not complain when it discovered that the computer system, in fact, did not meet its overall requirements.