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

Rolls Building
Fetter Lane,
London, EC4A 1NL

Date: 2 July 2024

Before :

MR JUSTICE RICHARDS

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Between :

(1) PFIZER INC. **(2) BIONTECH SE**	**Claimants**
- and –	
MODERNATX, INC.	**Defendant**
MODERNATX, INC	**Claimant**
- and –	
(1) PFIZER LIMITED **(2) PFIZER MANUFACTURING BELGIUM NV** **(3) PFIZER INC.** **(4) BIONTECH MANUFACTURING GMBH** **(5) BIONTECH SE**	**Defendants**

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Michael Bloch KC, Will Bordell and Sean Butler (instructed by **Taylor Wessing LLP)** for the **Pfizer parties**
James Segan KC (instructed by **Powell Gilbert LLP)** for the **BioNTech parties**
Anneliese Day KC and **Gillian Hughes** (instructed by **Freshfields Bruckhaus Deringer LLP)** for **ModernaTX, Inc**

Hearing dates: 2nd, 3rd, 7th and 8th May 2024

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Approved Judgment

This judgment was handed down remotely at 10.30am on 2 July 2024 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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Mr Justice Richards:

INTRODUCTION

1. The parties to this litigation are all pharmaceutical/biotechnology companies that were, at material times, engaged in the development and manufacture of COVID-19 vaccines based on mRNA technology.

2. ModernaTX, Inc ("Moderna") commenced proceedings against the Pfizer and BioNTech defendants (together "Pfizer/BioNTech") on 26 September 2022. By its Particulars of Claim dated 27 September 2022, Moderna alleged that Pfizer/BioNTech's "Comirnaty" vaccine, which uses mRNA technology, infringed two UK patents (the "Patents") owned by Moderna. Separately, Pfizer/BioNTech issued proceedings on 23 September 2022 against Moderna seeking among other matters, revocation of the Patents.

3. The claims that Moderna and Pfizer/BioNTech make against each other are being case-managed and heard together. A "technical" trial has taken place before Meade J on matters concerning the validity of the Patents. This judgment is not concerned with "technical" issues relating to the Patents. Rather, it deals with a defence that Pfizer/BioNTech advance in the event that the Patents are valid and infringed. That defence is based on a public statement that Moderna made on 8 October 2020 to the effect that, for so long as the pandemic continued, it would not enforce its COVID-19 patents against those making vaccines intended to combat the pandemic. I refer to that statement as the "Pledge", which is an expression that Pfizer/BioNTech have used to describe it. In using that term, I should not be taken as pre-judging the question whether the statement had any contractual effect, which is a matter of dispute between the parties.

RELEVANT FACTUAL BACKGROUND

4. The background facts set out below are not in themselves controversial although the parties differ as to the significance of those facts.

5. In late 2019 and early 2020, it became clear that there had been an outbreak of a novel coronavirus in China. An Emergency Committee (the "Emergency Committee") of the World Health Organisation ("WHO") was convened. On 30 January 2020, the Emergency Committee considered that the outbreak of COVID-19 was a "public health emergency of international concern" (a "PHEIC") and made recommendations as to an international response to that outbreak. The Director General of the WHO accepted those recommendations and COVID-19 was accordingly declared to be a PHEIC shortly after.

6. Efforts to identify and manufacture an effective vaccine were accelerated. In January 2020, Pfizer and BioNTech decided that they would work together to seek to develop a vaccine based on mRNA technology. At the time, Pfizer did not consider it obvious that the mRNA platform would be optimal, but that was the ultimate recommendation of Pfizer's research team. The rationale for the partnership between Pfizer and BioNTech was that it would bring together BioNTech's experience with mRNA technology with Pfizer's experience and resources in the large-scale manufacture of vaccines.

7. By July 2020, Pfizer/BioNTech had two promising candidates for a vaccine formulation, both based on mRNA technology. At a meeting in July 2020, Pfizer/BioNTech decided which of those to take into Phase 3 trials which commenced shortly after that meeting.

8. Also in July 2020, Pfizer/BioNTech entered into an agreement with the UK government for the supply of 30 million doses of an mRNA-based vaccine, conditional on regulatory approval or authorisation. Pfizer/BioNTech entered into that agreement with a view to manufacturing as many as 1.3 billion doses by the end of 2021.

9. On 9 September 2020, Pfizer/BioNTech announced that they had concluded exploratory talks with the European Commission for a proposed supply of 200 million doses of their vaccine that was under development, with deliveries expected to start by the end of 2020 subject to clinical success and regulatory authorisation.

10. On 8 October 2020, Moderna published the Pledge. The full text of the Pledge is set out in Annex 1 to this judgment and will be considered in detail later in this judgment. Among other statements, in the Pledge Moderna stated that "while the pandemic continues", Moderna would not enforce its COVID-19-related patents against "those making vaccines intended to combat the pandemic". While Moderna does not accept that the Pledge conferred any kind of consent on Pfizer/BioNTech, Moderna does accept that Pfizer/BioNTech were making vaccines intended to combat the pandemic. It is also common ground that Pfizer/BioNTech were aware of the Pledge from around the time that it was published.

11. Also in the Pledge, Moderna stated that it would on request be willing to license its intellectual property for COVID-19 vaccines to others for the "post-pandemic period". Therefore, whatever the precise effect of the Pledge, which will be considered later in this judgment, that effect was different for the period in which the "pandemic is continuing" as compared with the "post-pandemic period".

12. On 12 October 2020, Pfizer entered into supply agreements with the UK government pursuant to which it was to supply vaccine for use in the UK.

13. On 30 November 2020, BioNTech submitted an application to the European Medicines Agency for conditional marketing authorisation for a COVID-19 vaccine.

14. Pfizer/BioNTech have accepted in these proceedings that they advance no case to the effect that, in manufacturing a COVID-19 vaccine, they acted or relied on or were induced by the Pledge. They also accept that they did not communicate to Moderna that they would be carrying out actions that would be covered by Moderna's rights under the Patents on the basis of the Pledge.

15. The worldwide programme of vaccine production, that involved pharmaceutical companies other than just Pfizer/BioNTech, was successful. On 19 July 2021, England moved into "Step 4" of a roadmap out of lockdown with the majority of legal restrictions relating to the COVID-19 pandemic coming to an end.

16. By July 2021, there was a surplus of vaccine supply in certain countries, including the UK. An article published by the British Medical Journal on 27 July 2021 included the following paragraph:

> *The US, the UK, and the Netherlands face throwing away tens of thousands of covid-19 vaccine doses that are due to expire. The US had already thrown out more than 180 000 vaccine doses by the end of March, and some states, including Iowa and Arkansas, have warned*

> *that they have thousands more doses set to expire soon. Meanwhile, vaccine administrators in the UK now report that they too are having to discard doses, as strict rules around dosing intervals and fewer people coming forward for their first dose have led to supply far exceeding demand.*

17. As of 16 February 2022, 66% of the UK population as a whole had received three vaccine doses. A further 19% had received two vaccine doses and a further 6% had received one vaccine dose (leaving only 9% of the UK population unvaccinated).

18. All remaining COVID-19 legal restrictions were lifted in England, Northern Ireland, Scotland and Wales between February and March 2022.

19. On 7 March 2022, Moderna issued what it described as an update to the Pledge (the "March 2022 Statement"). The full text of the March 2022 Statement is set out in Annex 2 to this judgment. The meaning of the March 2022 Statement is disputed. Moderna relies on it as including, among other matters, a revocation of any promise not to enforce patents against those making COVID-19 vaccines except to the extent that those vaccines were being manufactured solely for use in 92 low- and middle-income countries (the "AMC 92"). Pfizer/BioNTech dispute this analysis of the March 2022 Statement.

20. It is common ground that Pfizer/BioNTech were aware of the March 2022 Statement at or around the time it was made but did not object to that statement at the time.

21. On 5 May 2023, the Emergency Committee advised the Director-General of the WHO that COVID-19 no longer constituted a PHEIC because, although the global risk assessment remained high, there was evidence of reducing risks to human health driven mainly by high population level immunity from COVID-19 arising from infection, vaccination or both.

THE PARTIES' POSITIONS AND STRUCTURE OF THIS JUDGMENT

22. In essence, Pfizer/BioNTech's case is that the pandemic was "continuing", and the "pandemic period" for the purposes of the Pledge continued at all times between the date of the Pledge and 5 May 2023. Accordingly, Pfizer/BioNTech argue that even if they would otherwise be infringing the Patents, the Pledge provides a defence to any allegation of infringement in that period on the basis that Moderna consented to acts that would otherwise constitute infringement under s60(1)(a) of the Patents Act 1977 (the "Patents Act").

23. Moderna disputes this analysis for the following broad reasons:

    i) First, it argues that, even if (without making any admission) the Pledge could be regarded as "consent" to <u>new</u> vaccine manufacturers infringing Moderna's patents, it was simply incapable in accordance with its terms of conferring "consent" on Pfizer/BioNTech who were already engaged in the making of COVID-19 vaccines, and contractually obliged to deliver such vaccines, at the time the Pledge was made.

    ii) Second, it argues that the Pledge was revoked by the March 2022 Statement. Therefore, even if the Pledge did confer "consent" on Pfizer/BioNTech, that consent ceased to be operative on 7 March 2022 at the latest.

iii) Moderna goes further. It argues that on its proper construction, the "pandemic period" specified in the Pledge was to be identified by reference to vaccine supply and so would come to an end on a country-by-country basis when vaccine supplies ceased to be a barrier to access to vaccines in any particular country. Accordingly, Moderna's position is that the pandemic was no longer "continuing" and the "pandemic period" had come to an end in the UK by July 2021 given the surplus of vaccines in the UK at that time. On that basis, any consent conferred by the Pledge came to an end by July 2021. Moderna does not seek relief for any of Pfizer/BioNTech's asserted acts of infringement that took place prior to 7 March 2022. However, in paragraph 15 of its Particulars of Claim, it expressly reserved the right to argue that any damages, or account of profits, that it is awarded in respect of post-March 2022 infringements should take into account the "springboard" advantage that Pfizer/BioNTech obtained from acts of infringement that took place before March 2022.

24. Pfizer/BioNTech deal with Moderna's argument set out in paragraph 23.ii) by arguing that the consent conferred by the Pledge was irrevocable because either:

i) The Pledge set out the terms of an offer, which Pfizer/BioNTech accepted by conduct, resulting in a binding unilateral contract governed by the law of Massachusetts (the "Unilateral Contract") that precluded Moderna from enforcing the Patents against Pfizer/BioNTech until the pandemic ended. Pfizer/BioNTech's position is that the law applicable to this Unilateral Contract is to be determined under UK law that preserves the effect of Regulation (EC) No 593/2008 ("Rome I").

ii) The Pledge amounted to a partial waiver of Moderna's rights in relation to the Patents that took effect under US federal law (a "Federal Law Waiver"), that being the proper law on an application of Rome I.

25. That introduced a further front of dispute based on conflict of laws. Moderna argues that neither a Unilateral Contract, nor a Federal Law Waiver can be relevant, reasoning that since the question of "consent" arises pursuant to the terms of the UK Patents Act and relates to allegations of infringement of UK patents, Regulation (EC) 864/2007 as retained in UK law ("Rome II") provides for only the UK law on consent to be relevant. If, contrary to that primary submission, the Unilateral Contract or Federal Law Waiver could have any bearing on the existence of "consent", Moderna (i) puts Pfizer/BioNTech to proof that Massachusetts law truly is the proper law of the asserted Unilateral Contract and (ii) denies that Rome I applies to determine the proper law of the Federal Law Waiver, asserting instead that Rome II provides for the law of the United Kingdom to be the proper law.

26. Even if Pfizer/BioNTech are right as to the relevance of Massachusetts law to the asserted Unilateral Contract, or US federal law to the asserted Federal Law Waiver, Moderna denies that there is any such contract or any such waiver.

27. There was virtually no dispute between the parties on matters of primary fact. The only witness evidence that was before me consisted of expert opinion evidence on matters of Massachusetts law and US federal law:

i) Pfizer/BioNTech relied on the expert evidence of Chief Justice Ireland on matters of Massachusetts law. Between 1997 and 2014, Chief Justice Ireland served as a Justice of the Massachusetts Supreme Judicial Court, the highest appellate court in the Commonwealth of Massachusetts. Between 2010 and 2014, he was that court's Chief Justice.

ii) Moderna relied on expert evidence of Mr Timothy Murray on matters of Massachusetts law. Mr Murray is a practising lawyer, a partner in the firm of Murray, Hogue & Lannis who are based in Pittsburgh, Pennsylvania and a member of the Pennsylvania Bar Association. Since 2004, Mr Murray has been involved in the authorship of the influential family of legal treatises known as *Corbin on Contracts* and has been the sole author of that family since 2015. He is also a co-author of *Corbin on Massachusetts Contracts* which was first published in 2021.

iii) On matters of US federal law, Pfizer/BioNTech relied on the evidence of Judge Kathleen O'Malley. Judge O'Malley served as a federal judge for over 27 years and between 2010 and 2022 served on the US Court of Appeals for the Federal Circuit, the only US Court of Appeals to hear appeals in patent matters. She has now retired from judicial office and is currently Of Counsel at Sullivan & Cromwell LLP.

iv) Moderna relies on the evidence of Professor Donald Chisum on matters of US federal law. Professor Chisum's career has largely involved the study of US federal law as an academic. He was Professor of Law at the University of Washington between 1969 and 1996 and at the University of Santa Clara from 1997 to 2006. He has retired from his professorial posts but continues to author the leading multiple-volume treatise on US patent law: *Chisum on Patents*.

28. I was entirely satisfied that all experts had the necessary expertise to give their opinion evidence and no-one suggested otherwise. I also considered that all experts gave their evidence in a dispassionate and scholarly way, seeking to assist the court on matters of some complexity. Later in this judgment I will explain why I prefer the opinions of certain experts over others but I have no criticism of the manner in which any of the experts gave their evidence.

29. In the light of that summary of the parties' respective positions, I will order this judgment as follows:

i) In Part A below, I will make findings as to the ordinary objective meaning of aspects of the Pledge and the March 2022 Statement.

ii) In Part B below, I resolve the debate between the parties on the application of Rome I and Rome II and thereafter the question whether it is relevant to consider whether there was a Unilateral Contract and/or a Federal Law Waiver.

iii) In Part C below, I determine whether there was a Unilateral Contract.

iv) In Part D below, I determine whether there was a Federal Law Waiver.

v) In Part E below, I draw the various findings together into conclusions.

PART A – OBJECTIVE INTERPRETATION OF ASPECTS OF THE PLEDGE AND MARCH 2022 STATEMENT

30. This part of my judgment is concerned only with the objective meaning of various parts of the Pledge. Later, I deal with questions of law such as whether, in the light of the objective meaning of the Pledge, it conferred any consent for the purposes of s60 of the Patents Act. It should not be assumed that all of the findings I make in this section are necessarily relevant to the questions of law I must determine. Pfizer/BioNTech's case, for example, is that the Pledge gave them the necessary consent even if the reference to forward-looking statements in the Pledge would be interpreted as giving Moderna complete freedom to change its mind at any point. I nevertheless consider it appropriate to make findings on all the matters below so that, if the matter goes further, those findings are available to a superior court.

Whether the Pledge is even capable of giving Pfizer/BioNTech consent

31. In her closing submissions on behalf of Moderna, Ms Day KC submitted that the court's task in construing the Pledge it is not to answer "general questions" about the Pledge but rather very specific questions that will determine whether the Pledge gives Pfizer/BioNTech specifically a defence to infringement. Once the question is posed in the right way, Moderna submits that, read objectively, the Pledge could not be regarded as conferring any sort of "consent" on Pfizer/BioNTech for the following reasons:

    i) There could only be "consent" to acts that would otherwise have infringed the Patents if Pfizer/BioNTech were using those patents. Yet Pfizer/BioNTech's position both at the time and now was that they were using their own technology rather than technology that was protected by valid Patents that Moderna held.

    ii) The Pledge contains no assurance that Moderna would refrain from taking action in relation to infringement before the date of the Pledge. Since there can be no suggestion that the Pledge conferred "retrospective" consent to infringing acts which Pfizer/BioNTech had already undertaken, the Pledge similarly cannot excuse Pfizer/BioNTech from the consequences of continuing those infringing acts. Accordingly, the Pledge did not apply to Pfizer/BioNTech in the same way as it would apply to a manufacturer who explicitly started using Moderna's patented technology in reliance on the Pledge.

    iii) The Pledge made it clear that it was being made so that Moderna's intellectual property rights did not constitute any barrier to the development of a COVID-19 vaccine. Moderna's intellectual property rights could not constitute any barrier to Pfizer/BioNTech's efforts in manufacturing a COVID-19 vaccine in circumstances where Pfizer/BioNTech (i) had already started the process of developing a COVID-19 vaccine and had entered into contracts for the provision of substantial quantities of that vaccine before the Pledge was even made and (ii) Pfizer/BioNTech were adamant that they were using their own intellectual property rights rather than those of Moderna.

32. Moderna rightly stresses that the Pledge must be read as a whole and that its meaning cannot be determined simply by reference to a few phrases considered in isolation. However, even reading it as a whole, I am unable to accept the arguments that are set out in paragraph 31 above.

33. Moderna's argument set out in paragraph 31.i) is, in my judgment, at odds with the ordinary objective meaning of the Pledge. Any person making, or considering making, COVID-19 vaccines could be expected to have a general understanding of patent law and litigation. Such a person would realise that it is often difficult to be certain whether a particular act does or does not infringe a particular patent. There can be doubt about the scope of a patent's claims. There can be doubt about the validity of a patent. Accordingly, Pfizer/BioNTech could quite genuinely consider that they were not infringing Moderna's patents but nevertheless be mistaken. The Pledge in its third paragraph states that "[b]eyond Moderna's vaccine there are other COVID-19 vaccines in development that may use Moderna patented technologies" (my emphasis). Moreover, the Pledge states that Moderna will not enforce patents "against those making vaccines intended to combat the pandemic". Accordingly, a person does not need actually to be infringing or even to think that they are infringing, in order to obtain the benefit of the assurance that Moderna's patents will not be "enforced". Rather, what matters for the purpose of the Pledge is the activity being undertaken, namely "making vaccines intended to combat the pandemic".

34. The difficulty with the argument in paragraph 31.ii) is that, in the third paragraph of the Pledge, Moderna refers to its knowledge that "there are other COVID-19 vaccines in development that may use Moderna patented technologies". A reasonable reader of the Pledge would realise that Pfizer/BioNTech's vaccine was in development at the time and that the development of that vaccine could lead to 1.3 billion doses being available in the UK alone. Moreover, public announcements on the development of Pfizer/BioNTech's vaccine made it clear that it used mRNA technology that was also a feature of the Patents. Clearly a reasonable reader of the Pledge could not know whether Pfizer/BioNTech's vaccine actually infringed Moderna's patents, but the possibility could not be excluded. Yet despite acknowledging awareness of Pfizer/BioNTech's vaccine as one of the "other COVID-19 vaccines in development", the Pledge does nothing in the very next sentence to exclude Pfizer/BioNTech from the benefit of the assurance not to enforce COVID-19 related patents. The Pledge does not differentiate expressly between persons who start making vaccines after the date of the Pledge and those who are already engaged in the activity. Both categories of person are, read objectively, persons "making vaccines intended to combat the pandemic" and so the target of Moderna's assurance.

35. Moderna's argument summarised in paragraph 31.iii) seeks to get around the difficulty that I have just identified by asserting that the exclusion of Pfizer/BioNTech from the scope of the Pledge is implicit, rather than explicit. I see the logic of Moderna's point that its patents did not represent an "IP barrier" to Pfizer/BioNTech's development of a vaccine given that Pfizer/BioNTech thought that they could develop that vaccine by reference to their own technology without needing to rely on that of Moderna. Perhaps Moderna could have formulated the Pledge as applying only to those for whom Moderna's patents would otherwise represent a barrier. However, that is not how it chose to formulate the Pledge. The Pledge, on an objective reading, applies to anyone "making vaccines intended to combat the pandemic". I do not consider that a reasonable reader of the Pledge would adopt a "purposive" reading of it under which Pfizer/BioNTech were excluded from its benefit by virtue of already being engaged in vaccine development.

The concept of the "pandemic period"

36. The statements of Moderna's intentions apply differently in relation to the "pandemic period" and the "post-pandemic period". Moreover, the assurance that Moderna would

not enforce its COVID-19 related patents was expressed to apply "while the pandemic continues". The Pledge gives little guidance on when the pandemic can be said to have come to an end.

37. Moderna argues that since the Pledge is focused on overcoming barriers to the development of a vaccine, it proceeds on the basis that the end of the pandemic, and so the start of the "post-pandemic period", can be determined by reference to vaccine supply. Therefore, it argues that the "pandemic period" would come to an end on a country-by country basis when vaccine supplies ceased to be a barrier to access to vaccinations in any particular country.

38. I do not consider that to be the correct reading of the Pledge, construing it objectively at the time it was made for two reasons.

39. First, Moderna's approach relies on the proposition that the "pandemic period" is to be determined on a "country-by country basis". In my judgment, a reasonable reader of the Pledge would regard that as a contradiction in terms. The stated rationale for the Pledge was that COVID-19 was a pandemic, affecting the whole world. Therefore, the natural reading of the Pledge is that the "pandemic period" represents the period during which COVID-19 represented a problem for the whole world and so did not end on a "country-by-country basis".

40. Second, the Pledge was given at a time when there was no vaccine for COVID-19 authorised for use in Europe or the United States. Therefore, a reasonable reader of the Pledge at the time it was given would not consider that wide availability of vaccines in any particular country, would necessarily signal the end of the "pandemic". At the time the Pledge was given, the possibility remained that vaccines, even if widely available, might be of limited efficacy. Even if vaccines were both effective and widely available, they would not bring the pandemic to an end unless they were widely used.

41. Accordingly, I do not accept Moderna's analysis to the effect that, properly construed, the "pandemic period" came to an end in July 2021 when vaccines were widely available, and indeed over-supplied, in the UK.

42. The question therefore remains as to what the concept of the "pandemic period" meant, properly construed at the time of the Pledge and when, on an operation of that construction, the "pandemic period" actually ended.

43. I conclude that, as a matter of construction, the Pledge gave no objectively clear definition of when the "pandemic period" would come to an end. A reasonable reader of the Pledge would consider the phrase in general terms as meaning the point in time at which COVID-19 ceased to be a worldwide problem. However, the reasonable reader could not divine from the Pledge any algorithm that would enable the date of the end of the pandemic to be determined with any certainty. A person making vaccines who wished to rely on the Pledge would need to understand with some precision when activities would become infringing since that manufacturer might well be making and selling vaccines in large quantities every day. It follows that the Pledge was uncertain on a matter that would be of some importance to anyone seeking to rely on it.

44. I take Pfizer/BioNTech to accept that, since the Pledge did not refer to the concept of a PHEIC, at the time the Pledge was made, a reasonable reader would not interpret the

Pledge as meaning that the "pandemic period" would end when the WHO determined that the PHEIC had come to an end. In any event, that is the effect of my conclusion set out in paragraph 43 above: the Pledge did not specify any algorithm for determining when the "pandemic period" came to an end and so did not specify that it would end when the WHO determined that the PHEIC had ceased.

45. Therefore, Moderna's analysis as to the end of the "pandemic period" is flawed for reasons that I have given. Pfizer/BioNTech's analysis suffers from the defect that the Pledge does not mention the concept of a PHEIC. Neither party presented any "compromise" formulation, supported by evidence, as to when the "pandemic period" ended and both parties proceeded on the basis that I should choose between the two formulations that were before me. If, notwithstanding my finding in paragraph 43 above, I need to choose between these competing formulations, I prefer Pfizer/BioNTech's analysis. It does at least focus on a measure by which the pandemic ceased worldwide and thus does not suffer from the difficulties with Moderna's analysis that I have highlighted in paragraphs 39 and 40 above.

The meaning of the reference to forward-looking statements

46. A good proportion of the Pledge is taken up by commentary on the "forward-looking statements" contained in the main body of the Pledge. The ordinary meaning of this commentary, and its effect, must be informed by the reason why such commentary is included in the first place.

47. I accept Judge O'Malley's evidence that the reason for the disclosure on "forward-looking statements" is to be found in a reform of US securities law contained in the Private Securities Litigation Reform Act 1995 (the "PSLRA"). Prior to enactment of the PSLRA, there was a perception that US issuers of securities were, in the words of a report at the time, being oppressed by the "routine filing of lawsuits against issuers of securities and others whenever there is a significant change in an issuer's stock price without regard to any underlying culpability of the issuer, and with only faint hope that the discovery process might lead eventually to some plausible cause of action". The PSLRA addressed this concern by providing a defence to any action based on an untrue statement of a material fact, or omission of a material fact, in a forward-looking statement provided that the statement is both (i) identified as a forward-looking statement and (ii) accompanied by "meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement".

48. Accordingly, I conclude that a reasonable reader of the Pledge would regard the disclosure on forward-looking statements as being included to take the benefit of the liability exclusion for which the PSLRA provides. I consider that such a reasonable reader would approach it as largely "boiler-plate" language.

49. However, a reasonable reader would not ignore the disclosure on forward-looking statements simply because of its boiler-plate nature. Rather, the reasonable reader would wish to understand which statements made earlier in the Pledge were identified as forward-looking statements and what, if any, significance that had on the meaning and effect of the earlier statements.

50. Applying that approach, the reasonable reader would conclude that the statement that Moderna "will not enforce our COVID-19 -related patents" was identified as a forward-

looking statement. That follows clearly from the very first sentence of the final paragraph of the Pledge. Having identified it as a forward-looking statement, the Pledge states that the statement is neither a promise nor a guarantee and that readers should not "place undue reliance" on it. The final sentence of the Pledge makes it clear that all forward-looking statements, which therefore included the statement as regards non-enforcement of patents, are "based on Moderna's current expectations and speak only as of the date hereof".

51. Read as a whole, the paragraph dealing with forward-looking statements makes two distinct but related points. First, Moderna reserves the right to change its mind in the future and so enforce its COVID-19 related patents even during the pandemic period. Second, even in the period before Moderna communicates an intention to change its mind, the pledge not to enforce patents is neither a promise nor a guarantee and a reader should not place undue reliance on it.

52. Pfizer/BioNTech suggest that these statements resonate only in the securities law arena and thus would be seen as directed only at investors or potential investors in Moderna. They posit the example of an investor who might see Moderna's prospect of obtaining revenue from AMC 92 countries as a particularly strong aspect of its business model. Such an investor might be reassured by statements in the Pledge to the effect that after the pandemic ceases, Moderna would continue to seek royalties, including in AMC 92 countries. An investor with that view might be aggrieved when, in the March 2022 Statement, Moderna decided no longer to seek royalties on COVID-19 vaccines intended for use in AMC 92 countries but, because of the disclosure on forward-looking statements in the Pledge, would have no right of action against Moderna.

53. However, these and other examples that Pfizer/BioNTech put forward do not persuade me that, read objectively, the disclosure on forward-looking statements was simply of no relevance to potential manufacturers of vaccines. Rather, I conclude that a reasonable reader of the Pledge, whether an investor in Moderna or a potential manufacturer of COVID-19 vaccines, would conclude that the statements conveyed the meaning set out in paragraph 51. Indeed, the examples that Pfizer/BioNTech put forward in their submissions seeking to limit the disclosure on forward-looking statements to matters of securities law all involved situations in which Moderna changed its mind.

54. Pfizer/BioNTech argue that it would make no sense for the Pledge to convey the meaning set out in paragraph 51. They submit that the stated purpose of the Pledge was to remove "potential or perceived barriers" to vaccine development and manufacture. If Moderna somehow retained the right simply to change its mind at any time, those barriers would remain as a putative vaccine manufacturer would be concerned even at the possibility of enforcement action being taken after spending potentially large sums on the development and manufacture of the vaccine in question.

55. Moderna objects that this argument involves a sleight of hand. Pfizer/BioNTech by their own admission were not relying on the Pledge when they decided to develop and manufacture vaccines. Therefore, Moderna suggests that since the question before the court revolves around whether Pfizer/BioNTech have consent under s60 of the Patents Act, how the Pledge would be read by someone other than Pfizer/BioNTech is simply irrelevant.

56. However, at this stage I am concerned only with the objective meaning of the Pledge. The Pledge takes the form of a public statement ostensibly made to the world at large. That aspect of the Pledge is, in my judgment, relevant to its objective meaning. The Pledge was not simply given to Pfizer/BioNTech, or indeed any other manufacturer or potential manufacturer of vaccines. It is, therefore, relevant when considering its objective meaning to determine whether it would make sense as a statement to the world at large.

57. However, I do not accept Pfizer/BioNTech's argument that the interpretation summarised in paragraph 51 deprives the Pledge of meaning. The Pledge set out a clear statement of Moderna's present intention not to enforce its COVID-19 related patents during the pandemic and to grant licences relating to those patents for the post-pandemic period. If a potential vaccine manufacturer wished to use Moderna's patents, and needed certainty as to Moderna's stance, it would realise from the Pledge that it was likely to obtain a favourable response if it approached Moderna asking for a contractual forbearance to sue during the pandemic period and a contractual licence afterwards. Such a contractual arrangement could deal with the uncertainties posed by the Pledge as to precisely when the "pandemic period" would end. Therefore, notwithstanding the points made in paragraph 51, the Pledge remained an objectively useful statement by alerting readers to the possibility of entering into a favourable contractual arrangement with Moderna.

Whether the March 2022 Statement revoked relevant aspects of the Pledge

58. Moderna argues that, by the March 2022 Statement, it communicated a clear intention that:

    i) It would never enforce its patents for COVID-19 vaccines against companies manufacturing them for use in the AMC 92 countries provided that the manufactured vaccines were solely for use in those countries.

    ii) Except to the extent that the statement in paragraph i) above applies, Moderna was prepared to license its COVID-19 related patents on commercially reasonable terms.

    iii) However, it would enforce its patents against any person manufacturing vaccines for use otherwise than in AMC 92 countries who did not have a licence of the kind referred to in paragraph ii).

59. Pfizer/BioNTech do not dispute the propositions set out in paragraph 58.i) or paragraph 58.ii). Pfizer/BioNTech's arguments that Moderna was not entitled to make the statement set out in paragraph 58.iii), because it was already bound by statements to the contrary that were either contractual or involved a Federal Law Waiver, will be considered later in this judgment. In this section, I address Pfizer/BioNTech's arguments that, read objectively, the March 2022 Statement was insufficiently clear to convey the meaning set out in paragraph 58.iii).

60. Pfizer/BioNTech's first argument is that the March 2022 Statement does not say in terms that the "pandemic period" referred to in the Pledge is over. That is correct but it does not render any aspect of the March 2022 Statement unclear. As I have explained, the Pledge itself envisaged that Moderna was free to change its mind on statements made in

the Pledge. Accordingly, Moderna's entitlement to change its mind did not depend on the "pandemic period" having ceased.

61. Next, Pfizer/BioNTech argue that the March 2022 Statement is presented as an "update" to the Pledge, a presentation that is inconsistent with a revocation of it. I do not accept that. The March 2022 Statement did "update" the Pledge by i) going beyond the Pledge by stating that patents would never be enforced to the extent that vaccines were manufactured solely for use in AMC 92 countries but ii) withdrawing the statement in the Pledge to the effect that Moderna would not enforce its patents during the pandemic period. Moderna was not withdrawing the Pledge wholesale and so the description of the March 2022 Statement as an "update" was objectively comprehensible.

62. Pfizer/BioNTech also argue that the statement in the sixth paragraph to the effect that Moderna "expect those using Moderna-patented technologies [to] respect [its] intellectual property" would be read as a statement that licences are needed for the post-pandemic period and as saying nothing about Moderna's stance on enforcement during the pandemic period itself. If that phrase were read purely in isolation, I could perhaps understand this argument. However, the March 2022 Statement contains a line of reasoning that points firmly against this interpretation. Read as a whole, the March 2022 Statement explains Moderna's view that AMC 92 countries were in a different position from the rest of the world. That different position explains Moderna's stance that it would never enforce its patents for COVID-19 related vaccines to be used only in AMC 92 countries. However, circumstances in other countries are different both i) from those in AMC 92 countries and ii) from those in existence at the time of the Pledge as "[i]n non-AMC 92 countries, vaccine supply is no longer a barrier to access". Both of those differences are expressed to justify and explain Moderna's decision to require anyone using Moderna's COVID-19 related patents in vaccines intended for use in non-AMC 92 countries to have a licence on "commercially reasonable terms" or otherwise face infringement proceedings. Pfizer/BioNTech's interpretation fails to give effect to this chain of reasoning.

63. I am reinforced in my conclusion by evidence that this was how the March 2022 Statement was perceived at the time. On 7 March 2022, the very date on which the March 2022 Statement was made, Peter Loftus wrote an article in the Wall Street Journal. In that article, he explained that:

> *Moderna Inc. said it will never use its COVID-19 vaccine-related patents to stop others from manufacturing its vaccine in more than 90 low- and middle-income countries, but signaled it was prepared to begin enforcing patents in wealthier countries.*

64. Pfizer/BioNTech seek to present this as simply an incorrect interpretation of the statement by a particular journalist. However, the article quotes Moderna's Chief Executive, Stéphane Bancel, as saying:

> *If people have used, or are using our technology to make a vaccine, I don't understand why, once we're in an endemic setting where there's plenty of vaccine and there is no issue to supply vaccines, why we should not get rewarded for the things we invented.*

65. These contemporaneous statements simply confirm what I consider to be the natural and ordinary meaning of the March 2022 Statement read objectively. I accept Moderna's interpretation of that statement that I have summarised in paragraph 58.

PART B – CONFLICT OF LAW ISSUES

66. It is common ground that principles I must apply are set out in the Rome I and Rome II Regulations which continue to have effect as Retained EU Law, at least insofar as is relevant to issues arising in this case. Therefore, while I recognise that I am applying principles of the UK statute law, I will refer in the analysis that follows to the text of the Rome I and Rome II Regulations which are effectively incorporated by reference into UK statute law.

Whether questions of foreign law are simply irrelevant

67. In its skeleton argument, Moderna submits that, "absent an express choice of law, a defendant to a patent infringement claim should not be permitted to rely on doctrines of foreign law as constituting consent for the purposes of s60 of the Patents Act when no equivalent doctrine in English law, capable of giving rise to consent for these purposes, would apply".

68. Pfizer/BioNTech characterise this argument as being to the effect that s60 is an exclusive code, governed entirely by UK law, that leaves no room for an analysis of foreign law concepts when deciding whether a patentee has consented to otherwise infringing acts unless the parties agree expressly that the presence or absence of consent is to be determined in accordance with foreign law. I am not myself sure that Moderna's submission went as far as that. However, in case it did, I will deal with it.

69. In my judgment the position is as follows:

    i) The question whether Moderna has given consent to what would otherwise be infringing acts of Pfizer/BioNTech is a question to be answered by the application of s60 of the Patents Act. That involves the application of the UK statutory concept of "consent". Moderna and Pfizer/BioNTech cannot "contract out" of UK law by providing for the question of infringement of the Patents to be determined otherwise than in accordance with UK statute law.

    ii) To establish that the necessary "consent" is present, Pfizer/BioNTech will necessarily be seeking to establish the presence of particular facts including, but not limited to, statements that Moderna has made.

    iii) In principle, the facts on which Pfizer/BioNTech rely as establishing s60 "consent" can include matters of foreign law. For example, Pfizer/BioNTech can argue that the consent in question is given, irrevocably, by a contract that is governed by foreign law, even if that contract does not contain an express choice of law clause.

    iv) Once I have decided which, if any, of the facts on which Pfizer/BioNTech rely are established, I must then decide whether those facts establish the existence of "consent" as that word is understood for the purposes of s60 of the Patents Act.

70. The proposition set out in paragraph 69.i) follows from Article 8 of Rome II which, by Article 8(3) precludes any derogation from the principle that questions of infringement of the Patents are to be determined in accordance with UK law. The proposition set out in paragraph 69.ii) above is obvious and uncontroversial.

71. Pfizer/BioNTech approached Moderna's submission summarised in paragraph 67 on the footing that Moderna is arguing that a foreign law agreement is only capable of establishing the facts necessary to amount to "consent" for the purposes of s60 if that agreement contains an express choice of law clause. If that was Moderna's position, I disagree and I do not consider the proposition to be established by the judgment of Arnold J (as he then was) in *HTC Corporation v Nokia Corporation* [2013] EWHC 3247 (Pat) to which Moderna referred. I see no reason why a person accused of infringing a UK patent could rely on a foreign law licence agreement with an express choice of law clause as establishing (irrevocable) consent, but could not rely on Rome I to establish the existence of a foreign law licence agreement with no express choice of law clause and argue that the (irrevocable) consent came from that licence agreement.

72. Applying the principles set out in paragraph 69, I see no reason why Pfizer/BioNTech are precluded from arguing that there was a unilateral contract, taking effect under the law of Massachusetts, under which Moderna was precluded from enforcing its COVID-19 related patents against Pfizer/BioNTech during the pandemic period. The existence of such a contract on its own would not be dispositive of the question since it would remain to be determined whether it operated to confer "consent" on Pfizer/BioNTech for the purposes of s60. However, I see no reason why I should simply exclude from consideration all possibility of a unilateral contract.

73. I find the arguments based on the Federal Law Waiver more difficult. As will be seen, I am not satisfied that, even if a US federal court would in an action for infringement of US patents, regard Moderna as having waived its rights, that has any bearing on the UK-law question of whether there was "consent" when an English court is considering possible infringement of UK patents. However, that is a reservation as to the correct outcome following an application of the principles in paragraph 69.iv). I do not consider that Pfizer/BioNTech are precluded from making arguments based on a possible Federal Law Waiver simply on the basis that those arguments involve propositions of foreign law. I will, therefore, consider Pfizer/BioNTech's arguments in this regard.

The correct approach to the identification of applicable law

74. At the second stage that I have identified in paragraph 69.ii) above, Pfizer/BioNTech seek to establish either (i) that Moderna was party to the Unilateral Contract that precluded it from suing for infringement of the Patents or (ii) that Moderna made a Federal Law Waiver to similar effect. The question therefore arises as to which jurisdiction's law is relevant to the asserted Unilateral Contract or the asserted Federal Law Waiver.

75. In this regard, the following propositions of law were common ground:

    i) The first step is to "identify (at a relatively abstract level) the essential factual and legal characteristics of the obligation or obligations relied on" (see 32-033 of Dicey, Morris & Collins on Conflict of Laws Sixteenth Edition ("*Dicey & Morris*")).

ii) Having done so, I should categorise the asserted obligations as being either "contractual" in nature, in which case the provisions of Rome I should be applied to determine the applicable law, or as "non-contractual" in which case the provisions of Rome II should be applied. (Neither side argues that the asserted obligations fall outside both Rome I and Rome II).

iii) The concept of "contractual" and "non-contractual" obligations are autonomous in the sense that their obligations do not depend on the way in which any particular legal system would characterise the obligation in question.

The governing law of the asserted unilateral contract

76. It is clear that the asserted Unilateral Contract should be analysed as a "contractual" obligation for the purposes of Rome I. There is no suggestion that there has been any express choice of law by the parties in relation to that contract. None of the considerations set out in Article 4(1) of Rome I applies in the circumstances of this case. Accordingly, the starting point is that the choice of law should be determined by an application of Article 4(2) of Rome I by identifying the country in which the "party required to effect the characteristic performance of the contract has its habitual residence".

77. While Moderna denies that there is any Unilateral Contract, it has accepted that, if there is such a contract, Moderna was the party required to effect characteristic performance of it.

78. It follows that, as regards the asserted Unilateral Contract, the task is to identify the "country" in which Moderna has its habitual residence. By Article 19(1) of Rome I, its place of habitual residence is to be the place of its "central administration". In its pleadings, Moderna accepts that its place of administration is located in Massachusetts.

79. The concept of a "country" is undefined in both Rome I and Rome II. Moderna does not disagree with Pfizer/BioNTech's proposition that the term should take its conventional meaning in private international law as meaning a territorial unit with its own rules of law (see 1-021 and 1-023 of *Dicey & Morris*). Even though the concept of a "country" generally is not defined, Article 22 of Rome I does make provision for the treatment of federal states in the following terms:

> *Where a state comprises several territorial units, each of which has its own rules of law in respect of contractual obligations, each territorial unit shall be considered as a country for the purposes of identifying the law applicable under this Regulation.*

80. It is common ground between the experts that the state of Massachusetts has its own rules of law relating to contractual obligations. Accordingly, the reasoning in this section leads to the conclusion that the governing law in relation to the asserted Unilateral Contract is the law of the state of Massachusetts.

The governing law of the asserted Federal Law Waiver

81. I do not consider that I need to determine whether the asserted Federal Law Waiver falls within the scope of Rome I or Rome II. First, as I explain below, even if the Pledge did answer to the concept of a waiver of rights under US federal law, that would not alter the analysis of the central question of "consent" that arises under s60 of the Patents Act.

Second, also as explained below, I do not consider that the Pledge answers to the US federal law concept in any event. In those circumstances, I propose to proceed on the basis, without determining the matter, that Rome I requires the asserted Federal Law Waiver to be analysed by reference to US federal law.

PART C: WHETHER THERE IS A UNILATERAL CONTRACT UNDER MASSACHUSETTS LAW

Introduction

82. To determine whether there is a unilateral contract under Massachusetts law, I must first make findings as to relevant aspects of Massachusetts contract law and then apply that law to the facts of this case.

83. When ascertaining relevant principles of Massachusetts law, I will decide how the highest court in Massachusetts would determine matters in dispute today (see for example, [106] of the judgment of Cockerill J in *Deutsche Bank AG London v Comune di Busto Arsizio* [2021] EWHC 2706 (Comm)). Previous authorities are, of course, relevant to that question.

84. The parties helpfully prepared a statement setting out those principles of US federal law and Massachusetts law on which they agreed, and those that were in dispute (the "Joint Statement"). Paragraphs 85 to 92 below set out agreed propositions of Massachusetts state law that will put my analysis on the unilateral contract issue into context.

85. There is no single body of "United States law". Rather, the laws applicable in the United States comprise federal law, which applies equally throughout the United States, and state law which applies only in the relevant state. Contract law is regulated by each individual state's law.

86. That said, contract law in the United States is broadly uniform (but not identical) across the various states and is periodically summarised in restatements published by the American Law Institute. The first such restatement (the "Restatement (First)") was published in 1932. The second such restatement (the "Restatement (Second)") was published in 1981.

87. Massachusetts contract law is not codified in any statute but rather, to the extent relevant to the issues arising in this case, is set out in case law. The relevant courts in which binding principles of Massachusetts contract law are formulated are the Supreme Judicial Court (the highest court of appeal in Massachusetts) and the Appeals Court (the lower appellate court in Massachusetts). In some instances, trial court judges at first instance issue written opinions but these opinions are persuasive only and not binding authority.

88. Judgments of the Supreme Judicial Court are binding both on the Appeals Court and on first instance courts in Massachusetts. Judgments of the Appeals Court are binding on first instance courts. The Supreme Judicial Court is not bound by its own decisions and is free to depart from them. In deciding whether to depart from a previous decision on a matter of contract law, the Supreme Judicial Court will treat the Restatement (Second) as a highly persuasive commentary. Therefore, although the Restatement (Second) cannot "overrule" a judgment of the Supreme Judicial Court, it is entirely possible that the Supreme Judicial Court could conclude that Massachusetts contract law is correctly

stated in the Restatement (Second) rather than in previous decisions of the Supreme Judicial Court.

89. The parties are not agreed on the extent to which the Restatement (First) is also a highly persuasive source of Massachusetts contract law on a par with the Restatement (Second).

90. For there to be a contract in Massachusetts law, there must be i) offer, ii) acceptance and iii) consideration. Massachusetts law does not require the presence of a further ingredient that will be familiar to English contract lawyers, namely an "intention to create legal relations" as a separate freestanding requirement. However, the combination of offer and acceptance require an objective manifestation of the parties' mutual assent to the exchange (i.e. a mutual assent to be bound).

91. Paragraph 11.5 of the Joint Statement recorded the experts' agreement that the existence of the basic elements of contract formation is assessed objectively (i.e. by reference to what a reasonable person in the position of the other party would conclude its counterparty's objective manifestations to mean), without reference to the parties' subjective intent. However, as will be seen, Mr Murray's expert report referred to a debate in Massachusetts law as to whether subjective intent could be relevant in some cases when deciding whether a person has accepted an offer of a unilateral contract, or has given consideration to a promisor under a unilateral contract. Chief Justice Ireland's expert report did not allude to this potential debate. Therefore, it was clear from the way the experts' evidence unfolded that they were not as agreed on this matter as paragraph 11.5 might suggest.

92. In principle, Massachusetts law permits the formation of unilateral contracts. Such a contract <u>can</u> be formed where an offeror promises a specified result if an offeree performs a specified act and the offeree both accepts the offer and furnishes consideration by taking the specified action with knowledge of the offer. However, if an offeree has manifested an objective intention not to accept such an offer of a unilateral contract (to which the experts referred as "disclaimer"), there will be deemed to have been no contract from the outset, even if the offeree has already performed the specified act in full.

93. I have in mind the entirety of the Joint Statement but the summary in paragraphs 85 to 92 should not be read as an attempt to summarise the entirety of the Joint Statement or all relevant aspects of Massachusetts contract law. Moreover, the expert reports of Chief Justice Ireland and Mr Murray revealed a disagreement on a number of matters of detail relating to applicable principles of Massachusetts contract law. There is no utility in me summarising all those points of disagreement. Rather, I set out the areas in which the parties disagreed on matters of Massachusetts contract law as pursued in their closing submissions which were as follows:

    i) **Offer**: Pfizer/BioNTech's position is that the Pledge set out a clear offer of a unilateral contract. Moderna denies this on the basis that the Pledge did not set out any objective manifestation of Moderna's willingness to form a contract.

    ii) **Acceptance**: Moderna's position is that, even to the extent that the Pledge contained an offer not to enforce the Patents against Pfizer/BioNTech, Pfizer/BioNTech's act in making vaccines to combat the COVID-19 pandemic was insufficient to constitute acceptance of that offer. Moderna asserts that to constitute acceptance, Pfizer/BioNTech's performance of the specified act (making vaccines)

had to be by reference to any offer that Moderna made and that since Pfizer/BioNTech were acting without reference to the Pledge, there was no acceptance. Pfizer/BioNTech's position is that there was acceptance because they performed the specified act with knowledge of the Pledge.

iii) **Consideration**: Moderna's position is that, for Pfizer/BioNTech's acts in making vaccines to constitute consideration that establishes the existence of a Unilateral Contract, those acts had to be induced by the Pledge. That requirement is not met since Pfizer/BioNTech were simply continuing to do what they were already doing. Pfizer/BioNTech deny the relevance of the concept of "inducement" and argue that they gave consideration for the promise set out in the Pledge by making vaccines.

iv) **Disclaimer**: Moderna's position is that, even if there were offer, acceptance and consideration, Pfizer/BioNTech had given a disclaimer of the kind summarised in paragraph 92 above.

Issues relating to offer

Applicable principles of Massachusetts law

94. The parties' pleadings and the reports of their experts revealed some disagreements on principles of Massachusetts contract law relating to "offer". For example, Chief Justice Ireland and Mr Murray were not agreed on the effect of a purported offer being uncertain, vague or indefinite on essential or material terms. Chief Justice Ireland's position was that only reasonable certainty of terms was needed to make such an offer capable of acceptance so as to form a contract. Mr Murray's position was that such defects in a purported offer meant that it was incapable of forming the basis of a binding contract.

95. Chief Justice Ireland and Mr Murray also disagreed on when an offer could be revoked. Chief Justice Ireland's position was that where an offer was to be accepted by performance, that offer could not be revoked once performance had started. Mr Murray's position was that an offer could be revoked at any time before full performance.

96. However, these areas of disagreement did not form the basis of extensive cross-examination and I do not, accordingly, feel equipped to resolve them. I proceed, therefore, on the basis of those propositions on the concept of "offer" on which the experts were agreed as set out in the Joint Statement. One such agreed proposition, set out at 13.4 of the Joint Statement is that there is no offer if a court determines that the language of a statement was not objectively intended to constitute an offer because, for example, it contains an effective disclaimer of an intention to be legally bound.

Application in this case

97. I have set out in paragraphs 46 to 57 what I consider to be the objective meaning of the "forward-looking statements" in the Pledge. In my judgment, those statements are inconsistent with an objective intention that Moderna be bound by a contractual promise not to enforce patents during the pandemic period.

98. As I have explained in paragraph 51, those forward-looking statements do not simply state that Moderna reserves the right to change its mind in the future. They go further by explaining that the statements of Moderna's stance on enforcement of its intellectual

property "are neither promises nor guarantees" and a reader should not place "undue reliance" on them.

99. That, in my judgment is inconsistent with any objective intention to make an "offer" that readers could accept by performance. The forward-looking statements do not simply reserve a right to revoke an offer, while remaining bound to any person who has accepted the offer prior to revocation. Rather, read as a whole, the Pledge manifests an objective intention to make no offer at all.

100. I am only reinforced in that conclusion by the uncertainty I have identified in the definition of the "pandemic period". I will not resolve the difference of opinion between Chief Justice Ireland and Mr Murray as to whether the presence of such uncertainty is necessarily fatal to the existence of an offer. However, Chief Justice Ireland accepted in cross-examination that Section 33 of the Restatement (Second) correctly stated Massachusetts law when explaining that the fact that one or more terms of a proposed bargain are left open or uncertain may show that there is no manifestation of intention to make an offer. The absence of certainty on the duration of the promise said to be contained in the Pledge militates against the Pledge constituting an "offer" that could itself be accepted.

101. There was, therefore, no "offer" that was capable of being accepted. However, I have heard extensive argument on matters of Massachusetts law going to "acceptance" and "consideration". Therefore, in the remainder of Part B I proceed on the basis that contrary to my conclusion, Moderna did make an offer. If there was such an offer, the parties were not agreed on what specified act needed to be performed in order to accept it. In its closing submissions, Moderna submitted that the specified act of acceptance did not extend to making vaccines intended to combat the COVID-19 pandemic by a person already engaged in making those vaccines.

102. I do not accept that submission. If there was an offer, the act that Moderna specified as constituting acceptance was "making vaccines intended to combat the pandemic". The Pledge does not contain any exclusion by reference to acts of vaccine manufacture that were going to be performed anyway. Moreover, as I have explained in paragraph 34, the Pledge itself acknowledges awareness that there were already "COVID-19 vaccines in development" such as those being developed by Pfizer/BioNTech. A reasonable reader would not, therefore, read the Pledge as excluding Pfizer/BioNTech from performing the designated act of acceptance by reference to those vaccines. Therefore, in the remainder of this section, I proceed on the basis that if there were an offer in the Pledge, it could be accepted by the act of "making vaccines intended to combat the pandemic".

Issues relating to acceptance

Findings on disputed principles of Massachusetts law

103. The evidence of Chief Justice Ireland was forthright. At paragraph 6.12 of his expert report, he stated that:

> *Massachusetts courts will not enquire into the offeree's motives for accepting the offer by performance. Performance of the act with knowledge of the offer is sufficient to form an enforceable contract.*

> *The test is a simple enquiry of fact to establish – yes or no – whether the offeree knew of the offer.*

104. In the same paragraph, he quoted an example from Section 53 of the Restatement (Second) to support that conclusion. That quoted example was of a situation where A offers a reward for information leading to conviction of a criminal. B, a friend of the criminal, knows of the reward and gives the information voluntarily. The Restatement (Second) states that B is entitled to the reward even though he acts because he thinks he is about to die and wants both to ease his conscience and to revenge himself for a beating received from the criminal.

105. I agree with Mr Murray that Chief Justice Ireland's forthright opinion paid insufficient regard to the requirement that, for a contract to be formed, there must be a "bargain in which there is a manifestation of mutual assent to the exchange" (see Section 17 of the Restatement (Second)). Section 23 of the Restatement (Second) makes the point that "It is essential to a bargain that each party manifest assent with reference to the manifestation of the other". Comment a. to this principle emphasises that "Two manifestations of willingness to make a bargain, though having the same terms, do not constitute a bargain unless each is made with reference to the other".

106. Chief Justice Ireland's position in cross-examination was that Section 53 of the Restatement (Second) explained that, where an offer of a unilateral contract was accepted by performance, the offeree would provide its "manifestation" of a willingness to make a bargain by reference to the offer simply by performing the stipulated act with knowledge of the offer. However, in my judgment, this opinion gave insufficient weight to matters referred to within Section 53 itself which indicated that the position is more nuanced. Section 53(1) articulates the general rule that an offer of a unilateral contract can be accepted by the rendering of a performance. However, it sets out two exceptions to that rule including, relevantly, Section 53(3):

> *Where an offer of a promise invites acceptance by performance and does not invite a promissory acceptance, the rendering of the invited performance does not constitute an acceptance if before the offeror performs his promise, the offeree manifests an intention not to accept.*

107. That introduces the possibility that, in appropriate cases, performance of the act with knowledge of the offer is not enough to constitute acceptance if there is otherwise some manifestation of an intention not to accept. Note b. to Section 53 makes that point expressly with further amplification coming from Note c. which reads as follows:

> *Where no promise by the offeree is contemplated, there is no problem of justifiable reliance by the offeror… The offeree's conduct ordinarily constitutes an acceptance in such cases only if he knows of the offer. His rendering of the invited performance with knowledge of the offer is a sufficient manifestation of assent, and enquiry into his motives is unnecessary. But the meaning of a non-verbal conduct is even more dependent on its setting than the meaning of words… The words or conduct of the offeree may show that he acts gratuitously or otherwise without reference to the offer. There is then no bargain. See Section 23.*

108. Moreover, while Chief Justice Ireland quoted one of the illustrations discussed in the commentary on Section 53, he did not mention the second. That illustration was in all material respects identical to that discussed in paragraph 104 above except that in that case, B is interrogated by the police and threatened with an arrest as an accomplice of the criminal (A). During the interrogation, without any mention of the reward, B is tricked into giving the information to clear himself. The conclusion of that illustration is that B is not entitled to the reward. In closing submissions, Pfizer/BioNTech suggested that this conclusion is unremarkable as the facts of the example are based on *Vitty v. Eley* 51 A.D. 44 (1900), a judgment of the Supreme Court of New York, the ratio of which was that involuntary acts do not amount to acceptance of a unilateral offer. That may be right, but the fact that Chief Justice Ireland did not address this example in his expert report, or explain why it was compatible with his approach summarised in paragraph 103, added to my impression that his expert report did not address some important matters.

109. I therefore conclude that Chief Justice Ireland's expert report omitted important issues of nuance concerning what precisely is necessary to constitute acceptance of a unilateral offer. By contrast, Mr Murray's expert report dealt with these matters of nuance in considerable detail. In my judgment, that provides a strong suggestion that Mr Murray's conclusions on the issue of "acceptance" should be preferred to those of Chief Justice Ireland.

110. Mr Murray said that his expert opinion on the relevant matter is properly captured in the following extract from *Williston on Contracts*, one of the most influential treatises on contract law in the United States, in its July 2023 update:

> *If an offeree in response to a bilateral offer said, "I accept your offer," the offeree would not thereafter be allowed to say that those words were not an acceptance because the offeree did not subjectively intend to accept the offer. By contrast, when an act is requested by the offeror and performed by the offeree, it may be shown that the performance of the act was not done with an intent to indicate assent to the offer. Even though the offeree knows of the offer, it may, if it chooses, do the act requested and still refuse to accept the offer. Thus, if an offeror offers a reward to any person who finds the offeror's watch, the finder may return the watch, yet affirmatively decline the offered reward. And even if the offeree makes no express disclaimer, the finding and return of the watch is an ambiguous act; it may mean that the offeree assents to the offer or merely that the offeree is honest and is returning the property but does not desire a reward. If, in a particular case, it indicates assent to the offer, there is a contract; but it may be evident, from all of the facts and circumstances surrounding the return of the watch, that the act did not mean assent to the offer in which case there is no contract. Thus, it may be said that when the offeree's outward manifestations are ambiguous or unclear and particularly when they take the form of conduct, an enquiry into the subjective intent, as well as into all of the other circumstances surrounding the outward manifestation, is appropriate.*

111. In cross-examination, it was put to Mr Murray that matters relating to the formation of contracts had to be determined objectively. In answering those questions, Mr Murray frequently commented on the difficulty of seeing into people's minds. He accepted that

the "manifestation of assent" that is essential to a bargain (see Section 23 of the Restatement (Second)) is concerned with a "manifestation" and not with "enquiring or seeking to open windows into men's souls" as Mr Bloch KC put it. However, I did not take him to depart significantly from the statement that I have set out in paragraph 110. His point, as I understood it, was that the only way one could ever make determinations about the subjective thoughts of another person would be by considering their acts and words as being the outward manifestations of those thoughts.

112. Mr Murray explained that there is an ongoing debate in the contract law of US states, including Massachusetts, having its origin in a debate between two great American contract scholars of the 20th century: Arthur Corbin of Yale and Samuel Williston of Harvard. Under the "traditional" (Williston-esque) view an offeree of a unilateral contract had to show that the act or forbearance was given with the intent of accepting the offer (see Section 55 of the Restatement (First)). Evidence of an offeree's subjective intention is, under the "traditional" view both relevant and admissible. Under the "modern" (Corbin-esque) view under which an objective theory of contract formation predominates, an offeree's subjective intention is not relevant. Rather, an offeree's intent to accept is presumed from performance of the specified act in the absence of words or deeds to the contrary.

113. Mr Murray said in his expert report that it is not clear whether the Massachusetts Supreme Judicial Court would adopt the "modern view" or the "traditional" view. Having heard the cross-examination of both experts, I have concluded that the Massachusetts Supreme Judicial Court would adopt the position summarised in paragraph 110 That represents something of a synthesis between the modern and traditional views since it focuses in the first instance on objective manifestations which are capable of setting up a presumption to the effect that performance of the act with knowledge of the offer constitutes acceptance while leaving open the possibility of considering subjective intent in cases of doubt. I note that Mr Murray was asked some leading questions in re-examination on the paragraph from *Williston on Contracts* which I quote in paragraph 110. However, that has not altered my conclusion since Mr Murray had referred with approval to the paragraph in his expert report in any event.

114. I am fortified in my preference of Mr Murray's evidence in this regard by the fact that Chief Justice Ireland accepted in cross-examination that there would be no acceptance of an offer of a unilateral contract "where the offeree acts without reference to the offer". In closing, Pfizer/BioNTech sought to downplay this, and other occasions on which Chief Justice Ireland accepted propositions put to him, on the ground that the question put had not addressed the matter of the rebuttable presumption. I am unable to accept that. Chief Justice Ireland had not, in his expert report, expressed the view that performance of a stipulated act, with knowledge of an offer, simply set up a rebuttable presumption of acceptance. His position was that this would necessarily amount to acceptance. It was that position that was explored in cross-examination and it was significant, in my judgment, that he did not mount a robust defence of it.

115. That still leaves a question on the burden of proof namely, if the presumption is engaged, an offeree has the burden of proving that it should not be rebutted or the offeror has the burden of proving that it should be. Chief Justice Ireland's approach did not require this issue to be addressed and so his expert report said nothing about it. Mr Murray did not express a concluded view on this issue in his expert report saying that the question "does not appear to be settled" as a matter of Massachusetts law". In his cross-examination Mr

Murray said that he did not know where the burden of proof lay saying that the question was "beyond my pay grade almost".

116. In another passage of cross-examination, he accepted that performance of the act created a rebuttable presumption of acceptance and said that "the offeror can come back and show … the act was gratuitous or was not in reference to the offer". That is perhaps suggestive of the offeror having the burden of proof, but it can also be interpreted as simply confirming that an offeror could seek to rebut the presumption if it wished to. Absent a clear retraction of the view set out in his expert report, I conclude that the incidence of the burden of proof is unclear as a matter of Massachusetts law.

117. Finally, I address the question of the nature of an intention that is capable of displacing the presumption. This matter was explored with Mr Murray in cross-examination. I took Mr Murray to accept that, if an offeree knew of the offer, thought it was a "good thing" from its perspective and so looked upon it positively when performing the "specified act" then the presumption of acceptance would not be rebutted even if the offeree had other motives for accepting the offer. I accept that to be Mr Murray's opinion on the evaluation of a hypothetical set of facts that was put to him. However, I do not consider his opinion was based on any proposition of Massachusetts law to the effect that the presumption is incapable of being rebutted whenever any offeree performs a specified act considering it to be a "good thing".

118. It will be observed that I have reached the conclusions set out above without myself quoting any extracts from the numerous authorities that were set out in the expert reports of Chief Justice Ireland and of Mr Murray. Both sides also referred to authorities in their closing submissions. Inevitably, Pfizer/BioNTech referred to authorities such as *Industrial America v Fulton Industries* 285 A2.d 412 (1971) which emphasised the relatively greater significance of objective manifestation over subjective intent in considering whether a unilateral contract has been formed by performance of a stipulated act. For its part, Moderna emphasised quotes from cases such as *Cottage Street Methodist Episcopal Church v Kendall* 121 Mass. 528 (1877) which, in referring to the requirement for a promisee, under a unilateral contract to perform the stipulated act "upon the faith of the promise", can be read as emphasising the importance of a subjective intention to accept.

119. Given that the authorities do not speak with one voice and given that there is evidence of a debate in US contract law between the "traditional" and "modern" approaches, I have concluded that there would be little to be gained from me performing my own exegesis of passages in the numerous authorities referred to. Rather, I consider that my conclusion should be substantially informed by the expert opinion from which I have benefited which was itself tested by reference to authorities in cross-examination. It is that expert opinion that has guided me to the conclusions expressed in this section.

Application to the facts

120. The act of acceptance specified in any offer constituted by the Pledge was "making vaccines intended to combat the pandemic" (see paragraph 102 above). Pfizer/BioNTech performed that act with knowledge of the Pledge. That sets up a presumption that it accepted Moderna's offer.

121. Pfizer/BioNTech's position in closing was that, since it had the benefit of a presumption in its favour, it did not need to establish anything further. Rather, it was for Moderna to displace the presumption. Pfizer/BioNTech argue that Moderna has made no attempt to advance a case that the presumption should be rebutted in its pleadings. Indeed, given Mr Murray's conclusion that the presumption would be intact even if Pfizer/BioNTech simply thought that the Pledge was a "good thing" and knew about it when it was manufacturing vaccines, Pfizer/BioNTech argued that it was difficult to see any rational basis on which the presumption could be rebutted.

122. I do not accept that analysis. Pfizer/BioNTech's position as set out in both its pleadings and Chief Justice Ireland's expert report was that simply by making vaccines intended to combat the pandemic, Pfizer/BioNTech had necessarily accepted Moderna's offer. I have not accepted that to be the case, concluding that there is more to acceptance than this. Given that Pfizer/BioNTech's pleaded case did not rely on any presumption established in their favour, I do not consider that Moderna can be criticised for not articulating a basis on which the presumption could be rebutted.

123. In any event, in my judgment the presumption is clearly rebutted irrespective of where the burden of proof on this issue lies. Pfizer/BioNTech's act in making vaccines to combat the pandemic was inherently ambiguous, just as the act referred to in the extract from *Williston on Contracts* of a person returning the lost watch. That ambiguity follows not from Pfizer/BioNTech's subjective intent, but rather from the fact that anyone seeing the act averred to be acceptance of Moderna's offer would know that Pfizer/BioNTech were already engaged in making vaccines, and had signed contracts for the delivery of such vaccines, even before Moderna made its offer. Given that ambiguity, further analysis is required of whether Pfizer/BioNTech were manifesting assent to Moderna's offer.

124. Even if that further analysis is performed entirely by reference to objective matters, it is clear that Pfizer/BioNTech were not manifesting assent to Moderna's offer. It was making vaccines that it would have made anyway both because it was, quite independently of the Pledge, in its commercial interests to do so and because it had signed contracts for the delivery of those vaccines.

125. Pfizer/BioNTech's admission that I have set out in paragraph 14 is, in my judgment, inconsistent with having any subjective intent to manifest assent to Moderna's offer by manufacturing COVID-19 vaccines. Accordingly, even if it were necessary to examine Pfizer/BioNTech's subjective beliefs, that examination would result in the presumption being displaced. I do not accept Pfizer/BioNTech's submission that the presumption is incapable of being rebutted on the basis that they must have considered the Pledge to be a "good thing" at the very least, so that Mr Murray's opinion summarised in paragraph 117 is engaged. As I have explained, that was Mr Murray's view on an approach to a hypothetical set of facts rather than an opinion on Massachusetts law.

126. Pfizer/BioNTech did not accept any offer that Moderna made in the Pledge.

Consideration

127. Both parties' experts accepted that the issues relevant to "consideration" were largely identical to those relevant to "acceptance". That is scarcely surprising given that Section 50(2) of the Restatement (Second) says that, in cases where an offer invites acceptance

by performance "… the act requested and performed as consideration for the offeror's promise ordinarily also constitutes acceptance".

128. Accordingly, Chief Justice Ireland's opinion on the need or otherwise for performance of the specified act to be "induced" by the offer (a concept on which Moderna relies as part of its case on "consideration") was contained in the section of his report dealing with "acceptance". Mr Murray accepted in cross-examination that the authorities he had considered in connection with "acceptance" were largely identical to those he looked at in connection with "consideration".

129. In view of the experts' agreement that the issues of "acceptance" and "consideration" largely overlapped, I will not deal with the question of consideration separately. Rather I conclude that the same reasons that led me to decide that Pfizer/BioNTech did not accept any offer that was made would have led me to conclude that they gave no consideration for any such offer either.

Disclaimer

130. I do not consider that there is any need to consider the question of disclaimer separately either. Since there was no offer, acceptance or consideration, I conclude that there was nothing that Pfizer/BioNTech could have disclaimed. I will, however, note briefly my conclusion that Pfizer/BioNTech's act in denying infringement of the UK Patents in these proceedings did not constitute a disclaimer of an intention to accept any offer that Moderna made. That is for the simple reason that, if there was an offer, the stipulated act of acceptance was making vaccines to combat the pandemic. Denying infringement of the UK Patents was not inconsistent with acceptance of an offer made in those terms.

PART D – FEDERAL LAW WAIVER

Introduction

131. The propositions of US federal law set out in this introduction are drawn from the Joint Statement and are, except where indicated otherwise, common ground between the parties.

132. Patent law in the United States falls within the subject matter jurisdiction of federal courts because US patent rights are federal law rights. Questions of substantive patent law, including whether a person has a defence to an allegation of infringement of a patent, are determined in the US federal courts which have three main levels: i) district courts (which function as trial courts), ii) circuit courts (which are the first court of appeal) and iii) the United States Supreme Court, which is the final court of appeal. The US Court of Appeals for the Federal Circuit (the "Federal Circuit") has the exclusive nationwide jurisdiction to hear appeals in patent cases, including appeals from district courts in cases of patent infringement. Decisions of the Federal Circuit are binding on district courts. Decisions of the US Supreme Court are binding on both the Federal Circuit and on district courts.

133. US federal law permits a person accused of infringing another's rights to rely on the waiver of those rights as a "judge-made affirmative defence". Such a waiver can be express or implied. However, since the concept of implied waiver is not relied upon in these proceedings, I say no more about it and focus on the concept of express waiver.

134. A waiver comprises the intentional relinquishment or abandonment of a known right and requires the following elements to be proved:

    i) the existence of a right which may be waived;

    ii) actual or constructive knowledge by the right holder of that right; and

    iii) an intention on the part of the right holder to relinquish the right, with full knowledge of the material facts.

135. Assertions of waiver under US federal law are most frequently made in the context of contractual rights, but are not limited to such rights.

136. A waiver can take effect under US federal law whether or not any person affected by that waiver relies upon it to their detriment.

137. Whether there is a waiver or not is to be determined by reference to the actions of the person holding the right, rather than the effect of those actions on the opposing party.

138. The intent of the allegedly waiving party is ascertained from the words used interpreted objectively. Thus, subjective intentions of the allegedly waiving party are not relevant. A waiving party cannot therefore prevent a waiver occurring by reference to a private mental reservation contrary to an intent to waive where its outward actions clearly indicate an intent to waive.

139. A waiver once made cannot be revoked, even if no consideration is given for the waiver. Although the experts were agreed on that proposition, they were not agreed on two related points:

    i) Judge O'Malley's position is that the terms of a waiver can specify the period for which it is operative. Once that period expires, the waiver no longer operates, not because it is revoked but because it ceases to apply in accordance with its terms. Professor Chisum does not agree.

    ii) There are circumstances in which a waiver can be "retracted" before the point at which a person has relied upon it to their detriment. The experts do not agree on the parameters within which a waiver can be "retracted" and whether or not reasonable notice of such a retraction is required.

Disputed propositions of US federal law: existence of waiver

140. By the conclusion of the cross-examination of Judge O'Malley and Professor Chisum, it was common ground that, under US federal law, a patent could fairly be regarded as a "bundle of rights". They also agreed that the essence of a patent holder's rights under a patent consists of the right to exclude others from performing acts of infringement that are specified in US federal law. They agreed that each infringement of a patent right is a distinct, actionable infringement with the patentee having the right, as part of its overall "bundle of rights", to choose to take action for some infringements and not for others. It was also common ground that US jurisprudence has analysed the grant of an express licence as a "mere waiver of the right to sue by the patentee" on the basis that a contractual licence passes no interest in the monopoly conferred by a patent (see the

judgment of the US Supreme Court in *De Forest Radio Telephone & Telegraph Co v United States* 273 US 236).

141. From these agreed propositions, Pfizer/BioNTech argue that a promise not to enforce patents for a period is capable of being analysed as an express waiver under US federal law. That promise, they argue, represents an irrevocable relinquishment of part of the overall "bundle" of rights. A patentee making such a promise does, of course, retain rights under the patent and, by limiting the promise to a period, is expressly retaining the right to enforce the patent once the period expires. However, argue Pfizer/BioNTech, there is nevertheless an irrevocable waiver of part of the bundle in the sense that the patentee forgoes forever the right to sue addressees of the promise for infringements of the patent committed during the period of the promise.

142. Moderna argues that this analysis involves a mis-labelling of key concepts. They argue that there is a conceptual difference between a mere "forbearance to sue" and a federal law waiver of rights. While acknowledging that a licence can be regarded as a "waiver" of a right to exclude in a general sense, that does not make a mere forbearance to exercise the right to exclude for a limited period a "waiver" in the specific US federal law sense.

143. In the remainder of this section, I will use the term "temporary forbearance to sue" to describe the kind of statement made in the Pledge. In doing so, I should not be taken as prejudging the question of whether there is a conceptual difference between a "temporary forbearance to sue" and a US federal law waiver which is one of the questions of US federal law that I must resolve.

144. I start with my overall conclusions and set out reasons for them in the remainder of this section:

    i) In the patent context, the US federal courts have analysed temporary forbearances to sue as conferring some legal rights on the addressee of the promise under doctrines of implied licence, or legal or equitable estoppel. In order for a promisee to obtain rights under these doctrines, it would need to show some sort of reliance on the statement of the forbearance to sue.

    ii) There is no US federal authority to the effect that a temporary forbearance to sue for infringement of a patent can be analysed only by reference to the concept of implied licence or legal or equitable estoppel.

    iii) However, there is no US federal authority in which a temporary forbearance to sue for infringement of a patent has been held to amount to a US federal law waiver of rights under that patent.

    iv) Therefore, Pfizer/BioNTech's analysis requires the English court to apply principles that the US federal courts have reached in other cases in order to decide whether a temporary forbearance to sue for infringement of a patent is capable of engaging the doctrine of express waiver. My conclusion on that question is "no".

145. Because of the point made in paragraph 144.iv), this court is particularly reliant on the expert evidence. Even if I considered every authority referred to myself, that would not provide the answer to the ultimate question I must determine. It therefore follows that, to a significant extent, I must consider how the respective opinions of Judge O'Malley and

Professor Chisum held up in cross-examination including by considering their overall logic and consistency.

146. The proposition I have set out in paragraph 144.i) was common ground between the experts. Indeed, Pfizer/BioNTech's case had previously involved the proposition that the Pledge gave it rights under US federal law by virtue of the doctrines of implied licence, legal estoppel and/or equitable estoppel. Those aspects of its case were abandoned before the trial but the expert reports demonstrated the need for "reliance" for any of these doctrines to apply.

147. Professor Chisum was clearly troubled by his concern that, if a temporary forbearance to sue for patent infringement was capable of engaging the US federal law doctrine of waiver of rights, a promisee would have a legal defence to allegations of infringement without detrimental reliance. He was concerned that this would dilute a central requirement of the doctrines of legal and equitable estoppel and implied licence which were the natural avenues for a promisee to explore in order to enforce a non-contractual forbearance to sue.

148. In his expert report, Professor Chisum suggested that, in order to address this concern, US federal courts might introduce a requirement for there to be detrimental reliance before a promisee could rely on a temporary forbearance to sue for patent infringement as constituting a federal law waiver of rights. He withdrew that opinion in cross-examination in the light of the judgment of the US Supreme Court in *Morgan v Sundance Inc* 596 U.S. 411 (2022) in which the Supreme Court held that the federal court should not formulate distinct rules of waiver applicable to distinct areas of law, although he remained of the view that a temporary forbearance to sue was incapable of amounting to a federal law waiver.

149. However, I nevertheless consider that Professor Chisum's reservation set out in paragraph 147 had force. The federal courts would not need to formulate a "bespoke" rule of waiver applicable to patent law in order to conclude that a temporary forbearance to sue is something other than a permanent relinquishment of rights. Rather, the federal courts would, in my judgment, be entitled to conclude that a temporary forbearance to sue does not answer to the definition of a federal law waiver of rights as there are other, more natural, means of characterising it (such as a legal or equitable estoppel or an implied licence). Adopting that approach could be regarded as preserving the requirement for detrimental reliance in cases of legal or equitable estoppel or implied licence, which would preserve the coherence of these doctrines.

150. The propositions set out in paragraphs 144.ii) and 144.iii) emerged following cross-examination of the experts. Naturally enough, Pfizer/BioNTech emphasise the proposition set out in paragraph 144.ii). Moderna emphasises the proposition set out in paragraph 144.iii).

151. Those propositions cannot, on their own, determine the matter. However, it is instructive to consider those cases in which an alleged express waiver of rights has been relied on in a patent law context.

152. Pfizer/BioNTech were able to identify just three cases: (i) *Winbond Electronics Corporation v International Trade Commission* 275F.3d 1344 (2001) ("*Winbond*") which was a judgment of the Federal Circuit, (ii) *Qualcomm Incorporated v Broadcom*

Corporation 548 F.3d 1004 (2008) ("*Qualcomm*") which was also a judgment of the Federal Circuit and (iii) *American Technical Ceramics Corp and another v Presidio Components, Inc* 2018 WL 1525686 ("*Presidio*"), a judgment of the District Court.

153. In *Winbond*, a standard-setting organisation ("SSO") was considering adopting a particular patented invention as an industry standard. While the SSO was performing its evaluation, the patentee stated that, if the invention was adopted as an industry standard, it would be willing to grant licences for a one-time fee to any manufacturer and to place the subject matter of the patent in the public domain. An administrative law judge had held that the patentee's statement amounted to an express waiver of rights. The Federal Circuit considered the question of waiver of rights in just one paragraph concluding that there was no waiver because the patentee's statements were conditional on the SSO adopting the invention as an industry standard and that condition was never satisfied.

154. Thus, *Winbond* did not involve any temporary forbearance to sue but instead addressed a promise, a component of which was to place the patent of invention in the public domain. The Federal Circuit did not need to make potentially ground-breaking determinations on the boundary between a temporary forbearance to sue and an express waiver of rights under federal law because, given the conditional nature of the patentee's promise, the question simply did not arise in the case before it. I regard *Winbond* as shedding relatively little light on the question whether a temporary forbearance to sue for infringement of a patent can constitute an express waiver of rights.

155. In *Qualcomm*, a patentee was obliged to disclose the fact that it held particular patents to an SSO. It deliberately failed to comply with its disclosure obligation in the hope that a particular standard, to which the patents were essential, would be adopted as an industry wide standard which would place the patentee in a strong position to require high royalties from implementers. The district court had held that the action of failing to disclose the patents involved the patentee making an express waiver of its rights as a matter of federal law. The Federal Circuit disagreed. It concluded that the very purpose of the non-disclosure was so that the patentee could obtain royalties from the patents in the future, which was completely incompatible with a conclusion that it had waived its rights.

156. Therefore, *Qualcomm*, like *Winbond*, did not involve a temporary forbearance to sue. In addition, as in *Winbond*, there was no need for the Federal Circuit to decide on the boundary, if any, between express waiver and doctrines of implied licence, and legal or equitable estoppel, since the conduct of the patentee was incapable as a matter of fact from constituting an express waiver.

157. *Presidio* was a judgment of a District Court on a summary judgment application. There was some evidence that a patentee had a policy of not enforcing its patent rights. The District Court declined to strike out a defence based on express waiver.

158. Being a judgment of the District Court, *Presidio* is of limited value as a binding precedent. Moreover, since it concerned summary judgment, it did not need to express any concluded view on the precise boundary between express waiver and forbearance to sue.

159. Overall, I conclude that the cases of *Winbond, Qualcomm* and *Presidio* do not advance the debate greatly and do not counteract the force of Professor Chisum's point

summarised in paragraph 147 above. While it is true to say that none of these cases rule out the possibility of a temporary forbearance to sue constituting an express waiver of rights, in none of the cases did the point arise for determination.

160. I also consider it significant that Judge O'Malley's analysis of whether a temporary forbearance to sue could constitute an express waiver in her expert report did not address the issue which troubled Professor Chisum. Of course, that is not determinative since conceptually Professor Chisum's concern might be groundless. However, it is instructive to consider the basis on which Judge O'Malley reached her conclusion.

161. Much of Judge O'Malley's analysis set out in her expert report involved largely uncontroversial principles. The truly controversial aspect of her expert report was contained in paragraph 7.7 (with an echo in paragraph 7.4) that read as follows:

> *the scope of the waiver depends on the specific facts of the case and on the interpretation of the words or writing used by the waiving party. A party may waive all of its rights under a patent, or it may choose to waive those rights only "in part"[23]. For example, a patentee might waive only the right to enforce their patent for a limited period of time or only under specific circumstances[24].*

162. Judge O'Malley's footnote 23 refers to the case of *Mallinckrodt, Inc v Medipart, Inc* 976 F.2d 700 (1992), a judgment of the Federal Circuit. However, that was not a case that dealt with the US federal law concept of waiver of rights. Nor was it a case that explored the boundary between express waiver and a temporary forbearance of a right to sue for patent infringement. The passage on which Judge O'Malley relied involved the Federal Circuit quoting the provisions of US federal law to the effect that a patent conferred the right to exclude others from making, using or selling the invention in the US for a period and then stating:

> *This right to exclude may be waived in whole or in part. The conditions of such waiver are subject to patent, contract, anti-trust and any other applicable law, as well as equitable considerations such as are reflected in the law of patent misuse. As in other areas of commerce, private parties may contract as they choose, provided that no law is violated thereby…*

163. Some aspects of the actual decision in *Mallinckrodt* were overruled by the US Supreme Court in *Impression Products, Inc v Lexmark International, Inc*. I agree with Judge O' Malley that the quote above was not overruled. However, the difficulty is that *Mallinckrodt* does not provide any real support for the conclusion that Judge O'Malley seeks to draw. The "waiver" that is referred to in the above extract from *Mallinckrodt* is the kind of "waiver" of a right to exclude that comes with the grant of a licence. It is not dealing with the federal law concept of express waiver of rights.

164. Judge O'Malley's footnote 24 was a reference to *Winbond*. Judge O'Malley confirmed that she had in mind the aspects of *Winbond* that endorsed the proposition that there could be a partial waiver of attorney-client privilege. However, that is some way from the present dispute.

165. I have concluded that Judge O'Malley's analysis of waiver of rights advanced some propositions of US federal law that were potentially far-reaching given Professor

Chisum's valid concern articulated in paragraph 147. However, Judge O'Malley's expert opinion did not fully explore the consequences of that analysis and, moreover, rested on the judgments in *Mallinckrodt* and *Winbond* that were concerned with different legal principles.

166. Finally, I note other materials on the concept of an express waiver that, while not determinative in themselves, are more consistent with Professor Chisum's analysis than with that of Judge O'Malley.

167. In *Fox v Commissioner of Inland Revenue* 874 F.2d 560, the Federal Circuit made the following observation on the nature of a US federal law waiver of rights:

> *Irrevocability is the essence of a waiver provision. ... For a waiver to be effective, the right allegedly waived must be gone beyond recall.*

168. I quite accept that it is possible to conclude that a temporary forbearance to sue for patent infringement satisfies this requirement. For the temporary period of the forbearance in question, it can be said that the patentee has irrevocably given up the right to sue for infringements in that period. However, I agree with Moderna and Professor Chisum that this approach would give the concept of "irrevocability" a somewhat strained meaning which the US Supreme Court would not adopt. A patentee forbearing to enforce a patent for a temporary period is more naturally to be regarded as having given up nothing that is "irrevocable" or "beyond recall" since, when the period expires, the patentee will again have all the rights conferred by the patent in question.

169. If the support for Judge O'Malley's alternative interpretation had been stronger, and if Judge O'Malley had been able to set out a more persuasive answer to Professor Chisum's concern articulated in paragraph 147, I might well have been attracted to the conclusion that a temporary forbearance to sue could be "irrevocable" in the sense outlined above. However, in the event I conclude that the weight of the various indications point in favour of Professor Chisum's analysis with the result that his analysis is more likely to be correct than that of Judge O'Malley.

Disputed propositions of federal law: "retraction"

170. As I have noted, both Judge O'Malley and Professor Chisum agreed that a waiver could not be "revoked". However, treatises, for example *Corpus Juris Secundum on Estoppel and Waiver* in Section 93, recognise that there are circumstances in which a waiver can be "retracted" before the other party has materially changed position in reliance thereon. It is fair to say that the distinction between "retraction" and "revocation" was not explored with either expert in great detail in cross-examination. However, Judge O'Malley did not express disagreement with the commentary in Section 93 of this treatise.

171. Judge O'Malley's principal position advanced in her expert report was that a waiver can itself stipulate the period for which it is to last. However, at paragraph 7.12 of her expert report she stated that:

> *Even where a waiver does not itself make it clear how long it lasts, courts have recognised that a waiver cannot be revoked "without first providing sufficient notice of the withdrawal and a reasonable time for*

> *plaintiffs to alter their conduct". In all events, revocation of a waiver must be "clear and unequivocal."*

172. I did not find that proposition straightforward to follow. Both experts appeared agreed that a waiver is irrevocable with the difference between them involving the question whether a waiver can be expressed, in its terms, to be time-limited. Therefore, it was not entirely clear to me how, if a waiver did not specify "how long it lasts", it could, on the parties' common position, be revocable at all and so I did not fully understand where the concept of "sufficient notice" fits in on Judge O'Malley's analysis.

173. Judge O'Malley referred to the authority of *La Guardia Associates v Holiday Hospitality Franchising, Inc*. 92 F.Supp.2d 119 (2000), a judgment of a District Court. Pfizer/BioNTech's skeleton argument referred to a further authority: *Liberty Bay Credit Union v Open Solutions, Inc*. 905 F.Supp.2d 389 (2012), but Judge O'Malley said in cross-examination that she had never read this case and I conclude, therefore, that she did not consider it to advance the debate and I focus on *La Guardia*.

174. *La Guardia* did not concern a situation where someone had purported to "retract" a waiver before the point at which another person had materially changed position in reliance on that waiver. Accordingly, it does not cause me to doubt the propositions that I have summarised in paragraph 170 above.

175. Nor do I consider that *La Guardia* stands for propositions on the US federal law of waiver set out in paragraph 7.12 of Judge O'Malley's expert report. In *La Guardia*, a party ("Holiday") established a practice of waiving contractual rights by giving a 60-day "grace period", rather than insisting on payment by the 15th day of each month. Importantly, there had not been a complete waiver of all rights under the contract: Holiday retained the right to the payments in question and had just waived rights to insist on payment by the 15th of each month. A question arose as to the extent of notice that Holiday needed to give of an intention to insist on its strict contractual rights going forward despite its waiver of earlier rights.

176. Answering that question involved no questions of the federal law of waiver. The historic effect of the US federal law waiver was dealt with briefly at [9] to [10] of the judgment, with the court confirming that the waiver of the right to insist on payment by the 15th of each month was irrevocable and the waiving party could not "reach back" to defaults that it had waived and rely on them as a basis for terminating the agreement. The court's conclusion that notice had to be given of Holiday's intention to insist, in the future, on its strict contractual rights was dealt with by the application of equitable principles applicable in the state of New York, having due regard to the nature of the contract in question (a franchise agreement).

177. I conclude that, to the extent that the Pledge involved a waiver of rights under US federal law, Moderna was entitled to retract it at any point before Pfizer/BioNTech materially changed its position in reliance thereon. Any such retraction had to be communicated to Pfizer/BioNTech to take effect, but there is no requirement that Moderna give reasonable notice thereof.

Application to the facts

178. I conclude that the Pledge was at most a temporary forbearance to sue for infringement of patents which did not constitute an express waiver of rights as a matter of US federal law.

179. Even if the Pledge was an express waiver of rights, it was validly retracted by the March 2022 Statement since Pfizer/BioNTech had not by that date materially changed its position in reliance on the Pledge.

PART E: CONCLUSIONS

"Simple consent"

180. Pfizer/BioNTech argue that, even absent any binding contract under Massachusetts law, and even absent any Federal Law Waiver, it had Moderna's consent to otherwise infringing acts between the date of the Pledge and 5 May 2023 when the PHEIC ceased.

181. Moderna denies that the Pledge was capable of conferring consent for the following reasons:

    i) The Pledge was a voluntary statement which made no reference to the UK or the Patents Act.

    ii) The Pledge referred to the "making" of vaccines and Pfizer/BioNTech have not, prior or subsequent to the Pledge, made any vaccines in the UK.

182. I have already concluded that the Pledge was "addressed" to Pfizer/BioNTech in paragraphs 31 to 35 above. The question now to be considered is whether the Pledge amounted to "consent".

183. I quite accept that there are situations in which there is a difference between a forbearance to sue and "consent". If A says to B that A will not sue in the civil courts if B uses A's car to drive to the supermarket, A might not be consenting to the use of the car in this way. However, the whole essence of a patent is that it confers a monopoly right to prevent others from exploiting the patented invention with that right only being enforceable by legal action against anyone infringing that right. Therefore, when a patentee says to another person that it will not "enforce" a patent, the fair interpretation of such a statement is that the other may exploit the patent without consequence since the monopoly rights that are the essence of the patent are not being asserted. Viewed objectively, I see no real difference between such a statement and a statement that a patentee "consents" to the exploitation of the patent.

184. That explains my reasons for rejecting the argument summarised in paragraph 181.i). Moderna's statement that it would not enforce its COVID-19 patents did not need to refer to the UK or to the Patents Act to amount to consent. By saying that it would not enforce its patents (not limited to patents protected under the law of any particular jurisdiction), Moderna was giving consent to acts that would otherwise constitute infringement of the (UK) Patents.

185. The Pledge did not contain any reference to the jurisdiction in which vaccines are made. Accordingly, the consent conferred by the Pledge was not conditional on vaccines being manufactured in any particular jurisdiction. I reject the argument in paragraph 181.ii).

186. In their skeleton argument, Pfizer/BioNTech argued that any consent conferred by the Pledge was irrevocable even if there was no unilateral contract under Massachusetts law and even if there was no Federal Law Waiver. That argument was not pursued in closing and I would have rejected it in any event. As a matter of ordinary English, "consent" is perfectly capable of being given and then withdrawn. I see no reason why it should be treated as having a different sense in s60 of the Patents Act.

187. Accordingly, in my judgment, on every day after the Pledge was published on which (i) the Pledge had not expired in accordance with its terms and (ii) Moderna had not yet revoked the Pledge, Pfizer/BioNTech had consent to what would otherwise be infringing acts under s60 of the Patents Act.

188. The Pledge did not expire in accordance with its terms before the March 2022 Statement (see my conclusion in paragraph 44 above). However, given my conclusions in paragraph 65, the consent given by the Pledge was revoked by the March 2022 Statement. In *United Wire v Screen Repair Services* [2001] RPC 24, Aldous LJ, said at [25] (emphasis added):

> *However, a person will infringe the patentee's rights if he does, without the patentee's consent, an infringing act.* ***Consent must mean contractual consent*** *and it would not be right to conclude that a patentee who sells a product thereby consents to infringing acts being carried out.*

189. Neither party referred to this authority in their written or oral submissions. I have concluded that Aldous LJ's statement is not inconsistent with my decision in paragraph 187. First, his statement was not part of the *ratio decidendi* since the case was not concerned with the question whether consent had to be contractual in order to "count" for the purposes of s60. Second, read in context Aldous LJ was simply concluding that, where a patentee enters into a contract for sale of patented goods, it does not follow that the contract amounts to consent to infringing acts. That conclusion is not inconsistent with the proposition that simple, non-contractual, consent is sufficient to provide a defence to acts which would otherwise be infringing.

190. Further, whilst it was not advanced by counsel for Pfizer/BioNTech in oral submissions, Pfizer/BioNTech's opening skeleton argument included a submission that if Moderna was entitled to withdraw its consent by way of the March 2022 Statement, it was required to give Pfizer/BioNTech a reasonable amount of time to cease their infringements. Pfizer/BioNTech relied on *Costa v Dissociadid Ltd* [2022] EWHC 1934 (IPEC) [71-82]. In that case, the conduct of the parties was found to have established a "bare licence" which would terminate only after a reasonable period had passed following notice of revocation (citing *Mellor v Watkins* [1873-74] LR9 QB 400).

191. However, the "bare licence" in *Costa* was in the nature of a contract, formed by conduct, containing a term requiring reasonable notice to be given of termination. As will be seen from the section that follows, I reject Pfizer/BioNTech's pleaded case on the existence of a contract. It follows that there is no contract conferring "consent" in this case and,

accordingly, no contractual requirement on Moderna to give Pfizer/BioNTech any kind of notice of revocation of the Pledge.

192. My conclusion on this topic is that Pfizer/BioNTech had non-contractual consent to perform acts that would otherwise infringe the Patents between 8 October 2020 and 7 March 2022.

Unilateral contract under Massachusetts law

193. There was no unilateral contract between Moderna and Pfizer/BioNTech under Massachusetts law because:

    i) Moderna made no "offer" to Pfizer/BioNTech;

    ii) Pfizer/BioNTech did not accept any "offer" that was made; and

    iii) Pfizer/BioNTech did not give consideration for any offer that was made.

194. Accordingly, there was no Massachusetts law contract to alter the conclusion set out under "Simple Consent" above that Moderna's consent was revocable and revoked by the March 2022 Statement.

US federal law waiver

195. A fundamental problem with Pfizer/BioNTech's case based on the Federal Law Waiver is that it reduces to a matter of labelling.

196. Even if the Pledge is labelled as a Federal Law Waiver that would simply provide an "affirmative judge-made defence" if proceedings were brought in the US federal court for infringement of US patents. However, these proceedings are taking place in England and concern infringement of UK patents. English law does not have the same concept of "waiver of rights" as appears in US federal law.

197. The contrast with the argument based on the Unilateral Contract is instructive. If there were a Unilateral Contract, it would be open to Pfizer/BioNTech to argue that the "consent" they had pursuant to that contract was irrevocable, at least until the contract expired in accordance with its terms. In that case, although the question before the court would still be concerned with "consent" under s60 of the Patents Act, the Unilateral Contract would give that "consent" an added dimension, in the nature of irrevocability, arising because the English courts are prepared in principle to give effect to contracts governed by foreign law.

198. The argument based on the Federal Law Waiver is incapable of giving rise to any added dimension of irrevocability because, at most, any Federal Law Waiver would operate as a defence and, moreover, only as a defence to infringement proceedings in the US federal courts.

199. Therefore, even if I had held that Moderna's actions answered to the definition of a "waiver of rights" under US federal law, that would not have altered my conclusions set out under "Simple Consent" above. Even if there were conduct amounting to a US federal law waiver, that would not as a matter of English law, render the "consent" that Moderna had given irrevocable.

200. In any event, the Pledge did not answer to the definition of a US federal law waiver. To the extent it did, the waiver was retracted in the March 2022 Statement.

ANNEX 1 –FULL TEXT OF THE PLEDGE

Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic

Moderna is a pioneer in the development of messenger RNA (mRNA) vaccines and therapeutics. From its inception in 2010, Moderna saw the potential of this new class of medicines to make a significant difference in patients' lives. With the support of our investors we have invested billions of dollars into research and development to make mRNA medicines a reality. One of the exciting discoveries advanced by Moderna was the combination of mRNA and lipid nanoparticles (LNPs) to make vaccines, and the demonstration of this potential in human clinical trials for 11 different infectious disease vaccine since 2015. Those discoveries and the expertise we developed have uniquely positioned Moderna to respond to the COVID-19 pandemic quickly. Information on our work towards a COVID-19 vaccine can be found here [a link to a website was provided].

As a company committed to innovation, Moderna recognizes that intellectual property rights play an important role in encouraging investment in research. Our portfolio of intellectual property is an important asset that will protect and enhance our ability to continue to invest in innovative medicines. A summary of our intellectual property can be found here [a link to a website was provided]. A selection of representative issued US patents relevant to our mRNA-1273 vaccine against COVID-19 is available here [a link to a website was provided].

Beyond Moderna's vaccine there are other COVID-19 vaccines in development that may use Moderna patented technologies. We feel a special obligation under the current circumstances to use our resources to bring this pandemic to an end as quickly as possible. Accordingly, while the pandemic continues, Moderna will not enforce our COVID-19 -related patents against those making vaccines intended to combat the pandemic. Further, to eliminate any perceived IP barriers to vaccine development during the pandemic period, we are also willing to license our intellectual property for COVID-19 vaccines to others for the post-pandemic period.

Moderna is proud that its mRNA technology is poised to be used to help end the current pandemic.

Forward-looking statements

This statement contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding Moderna's stance with respect to enforcement and licensing of its intellectual property rights during and following the COVID-19 pandemic. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "could," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this statement are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include those risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission

(SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at [a link to a website was given]. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this statement in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date hereof.

ANNEX 2 – FULL TEXT OF THE MARCH 2022 STATEMENT

As the pandemic surged in October 2020, we voluntarily committed that, "while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic." At that time, as a biotech company still working to develop its first commercial products, we understood that our portfolio of intellectual property was – and still is – an important asset that allowed us to attract investment. Such private investment made our mRNA technology possible. Further, that very intellectual property and associated rights protect and enhance our ability to continue to develop innovative medicines. Nevertheless, we felt and continue to believe that we have a special obligation to remove any perceived impediments created by our intellectual property rights so that the world could be vaccinated during the pandemic. That is why we have also licensed our patents to several manufacturing partners and raised more than $1.9 billion in private capital to scale up our manufacturing capacity so that we can now make billions of doses of our vaccine each year.

To underscore our commitment to low-and middle-income countries, Moderna is now updating our patent pledge to never enforce our patents for COVID-19 vaccines against companies manufacturing in or for the 92 low- and middle-income countries in the Gavi COVAX Advance Market Commitment (AMC), provided that the manufactured vaccines are solely for use in the AMC 92 countries.

This commitment builds on Moderna's efforts to ensure equitable access across the world, including through our agreement with COVAX to provide up to 650 million doses of our vaccine through 2022 to low- and middle-income countries at our lowest-tiered price, with tens of millions of additional doses committed directly to the African Union. Moderna has also announced plans to establish a state-of-the-art mRNA manufacturing facility in Kenya, investing up to $500 million to produce up to 500 million doses each year for the African continent.

In non-AMC 92 countries, vaccine supply is no longer a barrier to access. In these countries, the Company expects those using Moderna-patented technologies will respect the Company's intellectual property. Moderna remains willing to license its technology for COVID-19 vaccines to manufacturers in these countries on commercially reasonable terms. Doing so enables Moderna to continue to invest in research to develop new vaccines, prepare for the next pandemic, and meet other pressing areas of unmet medical need.