Neutral Citation Number: [2020] EWHC 261 (Pat)

Case No: HP-2019-000035

**IN THE HIGH COURT OF JUSTICE**
**BUSINESS AND PROPERTY COURTS**
**INTELLECTUAL PROPERTY LIST (CHANCERY DIVISION)**
**PATENTS COURT**
**SHORTER TRIALS SCHEME**

Royal Courts of Justice
The Rolls Building
7 Rolls Buildings
London, EC4A 1NL

Date: 14 February 2020

**Before** :

**MR ROGER WYAND QC, Deputy High Court Judge**

- - - - - - - - - - - - - - - - - - - - -

**Between :**

| | |
|---|---|
| **ELI LILLY AND COMPANY** | **Claimant** |
| **- and -** | |
| **GENENTECH, INC** | **Defendant** |
| **-and-** | |
| **ELI LILLY AND COMPANY LIMITED** | **Part 20 Defendant** |

- - - - - - - - - - - - - - - - - - - - -

- - - - - - - - - - - - - - - - - - - - -

**MR ANDREW WAUGH QC, MR JEFFREY CHAPMAN QC AND DR STUART BARAN** (instructed by **Allen & Overy LLP**) for the **Claimant and Part 20 Defendant**
**MR STEPHEN MORIARTY QC, MR MICHAEL TAPPIN QC AND MR WILLIAM DUNCAN** (instructed by **Marks and Clerk Law LLP**) for the **Defendant**

Hearing dates: 28 and 29 January 2020

- - - - - - - - - - - - - - - - - - - - -

# Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

## MR ROGER WYAND QC, Deputy High Court Judge :

1. This is the trial of a preliminary issue and a summary judgment application in an action brought by Eli Lilly and Company, (Lilly), for the revocation of European Patent (UK) No. 2784084 B, (the 084 Patent) in the name of Genentech Limited, (Genentech). Genentech are defending the action and have brought a Part 20 action against Eli Lilly and Company Limited for infringement of the 084 Patent. By an order of 22nd October 2019, Birss J directed that the Claimant's plea that certain matters are *res judicata*, as set out in paragraph 5 of the Claimant's Grounds of Invalidity, be heard and determined as a preliminary issue and that the Claimant's summary judgment application, consequential on success on that preliminary issue, be listed to be heard at the same time as the trial of the preliminary issue.

2. *Res judicata* is alleged to arise as a result of Arnold J (as he then was) having revoked European Patent (UK) No. 1641822 (the 822 Patent) of which the 084 Patent is a divisional. Arnold J held, in what I shall call the 822 Action, that if he had found the 822 Patent valid he would have found that Lilly had infringed it. Genentech was given permission to appeal by Arnold J on its draft Grounds of Appeal in so far as they raise issues of law or principle but no permission was given in respect of any finding of fact. Floyd LJ directed that Genentech should not be prevented from contending that factual findings of the Judge lacked any evidential basis.

3. Genentech lodged an appeal from the decision of Arnold J and that, I am told, has been set down for a hearing in January 2021.

4. On the 10th January 2020 the Technical Board of Appeal (the TBA) of the European Patent Office (the EPO) upheld the decision of the Opposition Division (the OD) of the 12th of October 2016 and revoked the 822 Patent on the ground that, as granted, it contained added matter, a ground that had been argued before Arnold J and rejected by him. I am told that no step has been taken by either party or the Court of Appeal to withdraw the appeal although the effect of the TBA decision is that the 822 Patent is to be treated as though it never existed.

5. The 084 Patent is entitled "Antagonist antibodies to IL-17A/F heterologous polypeptides". It stems from a PCT application filed in June 2004, claiming priority from US applications filed in July 2003.

6. The 822 Patent is entitled "IL-17A/F heterologous peptides and therapeutic uses thereof". It stems from the same PCT application and claims priority from the same US applications. Before Arnold J, Genentech did not seek to support the claims as granted but applied to amend the claims of the 822 Patent. He found them allowable with one minor change but held that they would not cure the invalidity. Genentech are applying to amend the claims of the 084 Patent. For present purposes there are no material differences between the specifications and claims of the 822 Patent as it was sought to be amended and the 084 Patent as it is sought to be amended.

7. In July 2017 Lilly commenced the 822 Action seeking a declaration of invalidity and an order for revocation of the UK designation of the 822 Patent and declarations of non-infringement of the 822 Patent in respect of Lilly's product Taltz®, which contains the antibody ixekizumab. Genentech counterclaimed for infringement of the UK designation of the 822 Patent by Taltz®. Lilly also sought declarations of non-infringement in respect of the French, German, Italian and Irish designations, as well as a Spanish equivalent. Those declarations were stayed by Birss J on 11 January 2018 when Lilly failed to give an undertaking that it would not put the validity of those patents in issue. The 822 Action came on for trial in January 2019 and

occupied the court for 12 days. It was one of the most complicated and expensive patent actions with the costs between the parties amounting to over £11 million (Lilly some £6 million and Genentech some £5 million). Arnold J observed in [3] of his judgment that:

> *3. It is pertinent to observe at the outset that this is one of the most complex patent cases I have ever tried (and I have considerable experience of trying complex patent cases). There are a large number of issues, and a formidable body of material addressing them. Some indication of this is provided by the following metrics. Lilly's written closing submissions run to 607 paragraphs and Genentech's to 423 paragraphs, and both documents incorporate by reference additional sections from the parties' respective opening skeleton arguments. There are 24 reports from nine expert witnesses running to 676 pages (including annexes, but excluding exhibits). The experts were efficiently cross-examined over seven and a half days. There are over 300 scientific papers (including a few abstracts) in the trial bundles (although I estimate that only about half were referred to), plus extracts from two books. I have done my best to take all this material into account; but I cannot possibly refer to all of it in this judgment. As will appear, I have been able to deal quite briefly with some of the issues. Even so, it cannot avoid being a lengthy judgment.*

8. Lilly says that it is in order to avoid a further costly and lengthy trial, exploring exactly the same issues, that they are seeking summary judgment based on issue estoppel and abuse of process arising from Arnold J's judgment in the 822 Action.

9. This litigation concerns the course taken by Lilly to clear the way of Genentech's patents and putative SPCs which it asserts over the Lilly product called Taltz®. Taltz® is a formulation of an antibody called ixekizumab and is the product of the wholly independent research of Lilly, as found by Arnold J in his judgment in the 822 Action. Genentech does not have any product on the market to which the 822 or 084 Patents relate.

10. The clinical and commercial importance of Taltz® is set out in Lilly's evidence on this application. In summary, Taltz® is authorised in the EU for the treatment of moderate to severe plaque psoriasis and for the treatment of adult patients with active psoriatic arthritis. In common with such rare successful drugs, massive resources were required to discover, develop and obtain regulatory approval for Taltz®.

11. The clinical benefits of Taltz® are said to be huge. As a result of its clinical importance Taltz® is a flagship product of Lilly and is said by Lilly to be of immense and incalculable value to Lilly's current and future business.

12. Because of its very considerable significance, securing commercial certainty that it is free to sell Taltz®, and doing so promptly, is crucial to Lilly. It is the reason (a) Lilly commenced proceedings against the 822 Patent; (b) why it commenced proceedings seeking a declaration of invalidity in respect of Genentech's SPC application based on the 822 Patent; (c) why it has commenced these proceedings against the 084 Patent; and (d) why it is important to Lilly to secure resolution of these proceedings as expeditiously as is possible.

13. Genentech has also commenced proceedings against Lilly's affiliates for infringement of the German designations of the 822 Patent and the 084 Patent in the Regional Court of Düsseldorf by Statements of Case dated 6 August 2019 and served between 21 August and 12 September 2019. Germany is Lilly's most important market in Europe for Taltz®. In that action, as in this action under the 084 Patent by Counterclaim, Genentech is seeking a final injunction against Lilly.

14. The threat of an injunction under the 822 Patent has now gone with the final revocation of the 822 Patent by the TBA. However, the threat of an injunction remains in these proceedings under the 084 Patent and the matter remains of the utmost urgency to Lilly.

15. Under German procedure, Lilly is unable to challenge the validity of the 084 Patent until the EPO opposition proceedings are over. Also, in Germany, the proceedings are 'bifurcated' whereby infringement and validity are not heard at the same time by the same court. As a result, Lilly faces the real threat that, if Genentech succeeds in its infringement case in Germany under the 084 Patent, as it did in the UK in the 822 Action, the two claim sets being essentially the same, without the ability to revoke the 084 Patent in Germany until the opposition proceedings have ended, Lilly may be required to remove Taltz® from the German market causing Lilly and patients very significant harm and damage.

16. The benefit of a judgment finding the 084 Patent invalid, for the same reasons as the 822 Patent, is said by Lilly to be that, under German case law, the German Regional infringement courts should consider decisions handed down by the European Patent Office or by courts in other EPC contracting states which essentially concern the same issue, and if necessary they have to address the grounds which led to a divergent result in the prior decision.

17. Because the UK Court already decided on the invalidity of the 822 Patent, a decision of the UK Court on a revocation action against the 084 Patent would allow the Düsseldorf Court to recognise the relevance of that earlier judgment on the 822 Patent for the invalidity of the 084 Patent.

**The Technical Background**

18. At the date of the PCT application, two proteins were known, referred to as IL-17A (or simply IL-17) and IL-17F. These are homodimers, i.e. IL-17A is made up of two identical IL-17A chains (and is sometimes referred to as IL-17A/A for that reason) and IL-17F (or IL-17F/F) is made up of two identical IL-17F chains.

19. The PCT application explained (in a passage that is to be found in [0015] of the 084 Patent) that it was known that IL-17A is a pro-inflammatory molecule produced by activated T cells that stimulates various cell types to produce other inflammatory cytokines and chemokines, including two known as IL-6 and IL-8. That passage went on to explain IL-17A's various known roles in the pathology of rheumatoid arthritis and stated that it was believed to play a key role in certain other autoimmune diseases, including psoriasis (citing certain papers). The application went on to explain (in a passage that is to be found in [0018]-[0019] of the 084 patent) what was known about IL-17F, including the fact that it appeared to have similar biological actions to IL-17A. It further noted that recently the inventors had observed that both IL-17A and IL-17F were induced in T cells by IL-23 (citing a 2003 paper by Aggarwal *et al.*). Genentech say that 2003-2004 was a period in which the understanding of the IL-17 / IL-23 system and its involvement in psoriasis and other autoimmune diseases was developing.

20. The application went on to describe (in a passage to be found in [0020] of the 084 Patent) the inventors' discovery of the production by activated T cells of a heterodimeric protein, made up of one IL-17A chain and one IL-17F chain, which they called IL-17A/F. That discovery is described in more detail in Examples 1 and 2 (see pages 74-86 of the 084 Patent). These examples show (i) that IL-17A/F is produced by activated T cells, (ii) that IL-17A/F induces the production of IL-6 and IL-8 and (iii) the production of a number of antibodies against IL-17A/F. The application stated that antagonistic antibodies to IL-17A/F will have utility in the

treatment of rheumatoid arthritis and other autoimmune diseases, including psoriasis. The plausibility of that statement in respect of psoriasis was an issue in the 822 Action.

21. The PCT application entered the European phase and underwent prosecution at the EPO. The first patent granted in the family based on the PCT application was the 822 Patent. As granted, the main antibody claim was claim 27, which was to:

*"An isolated antibody which specifically binds to the IL-17A/F heterodimeric complex according to claim 23 or claim 24 and which inhibits the activity of the IL-17A/F heterodimeric complex to induce production of IL-8 and IL-6."*

22. Once the 822 Patent was granted in May 2013 it was opposed by numerous parties (but not by Lilly). One of the grounds of opposition was added matter, and one of the points made by the opponents was that the PCT application did not disclose the combination of an IL-17A/F antibody and inhibition of IL-17A/F-induced IL-6 and IL-8 production. In response to the oppositions, Genentech advanced amended claims as main and auxiliary requests, but the requirement for the antibody to inhibit IL-17A/F-induced production of IL-6 and IL-8 necessarily remained. Claim 1 of the main request was:

"*An isolated antibody which specifically binds to an isolated IL-17A/F heterodimeric complex and which inhibits the activity of the IL-17A/F heterodimeric complex to induce production of IL-8 and IL-6, wherein the isolated IL-17A/F heterodimeric complex comprises SEQ ID NO:3 and SEQ ID NO:4 without their associated signal peptides, and further comprises two interchain disulphide linkages between SEQ ID NO:3 and SEQ ID NO:4; and wherein the antibody is either human or humanized."*

23. On 12 October 2016 the Opposition Division ("OD") held that the claims of the main and auxiliary requests were invalid for added matter, *inter alia,* because of the requirement in the claims for the antibody to inhibit IL-17A/F-induced production of IL-6 and IL-8. Genentech appealed.

24. Prior to grant of the 822 Patent Genentech had filed a divisional application stemming from the original application. In response to the finding of the OD on the 822 Patent, on 24 August 2017 Genentech filed amended claims for the divisional application which were designed to avoid the added matter objections that had been raised against the 822 Patent and upheld by the OD.

25. After further prosecution, the divisional application proceeded to grant in July 2019 as the 084 Patent. That has now been opposed (but not yet by Lilly). Claim 1 is in the following form:

*"An antagonist of an IL-17A/F polypeptide, wherein the antagonist is an anti-IL-17A/F antibody, wherein the antibody is a humanized or human antibody, and wherein the IL-17A/F polypeptide is:*
*an isolated polypeptide comprising:*
*(a) the amino acid sequence of an IL-17A/F polypeptide comprising SEQ ID NO:3 and SEQ ID NO:4; or*
*(b) the amino acid sequence of an IL-17A/F polypeptide comprising SEQ ID NO:3 and SEQ ID NO:4 lacking their associated signal peptides."*

26. The appeal from the decision of the OD on the 822 Patent was heard by the Technical Board of Appeal ("TBA") on 10 January 2020 (by this stage Lilly had intervened in the EPO proceedings). The TBA held that the 822 Patent was invalid for added matter because the application did not disclose the combination of an anti-IL-17A/F antibody and the inhibition of IL-17A/F-induced production of IL-6 and IL-8. The result is that the 822 Patent has been revoked for all EPC territories, including the UK, and is deemed never to have had any effect pursuant to Article 68 of the European Patent Convention.

27. The upshot is that Genentech's first granted patent for its invention has been held invalid because of the introduction into the claims of the feature of inhibition of IL-17A/F-induced production of IL-6 and IL-8. The difficulty for Genentech is that this is a case where the deletion of the added matter from the claims of the 822 Patent would be contrary to Article 123(3) of the European Patent Convention as it would extend the protection it confers by the removal of what is technically a limitation. Therefore, the added matter objection cannot be cured by amendment. The EPO system allows for the filing of divisional applications, which can allow inventors to avoid losing patents for their inventions in such circumstances, which is what Genentech has done, quite legitimately. The claims of the 084 Patent are free of the objection which the TBA held to be fatal to the 822 Patent.

28. A convenient comparison of the text of the specifications of the two patents is annexed to the Grounds of Invalidity. Unsurprisingly they are the same in all material respects with only insignificant differences which are not relied on to support the claims of the 084 Patent (nor could they be as it is not permitted to add matter from a parent application to a divisional, nor from one divisional to the next).

29. The claims are, therefore, for present purposes, the same as those already considered by Arnold J with only immaterial differences.

30. Before Arnold J, Genentech made no attempt to defend the claims as granted; see [179] of the 822 Judgment. Instead, Genentech presented an amended claim set which Arnold J sets out in [180] of the 822 Judgment.

31. At [618] of the 822 Judgment, Arnold J summarised his findings as follows:

> i. *Genentech's unconditional amendments to the claims are allowable, with the minor exception of "comprises" in new claims 1 and 14, but the conditional amendment to "consists of" is allowable.*
> ii. *Claims 1, 2, 13, 14 and 15 are obvious over US344, as are claims 12, 20 and 22 in so far as those claims are directed to RA.*
> iii. *Claims 1, 2, 13, 14 and 15 are novel but obvious over the IL-17A/A prior art, as are claims 12, 20 and 22 in so far as those claims are directed to RA.*
> iv. *Claims 12, 20 and 22 are insufficient for lack of plausibility in so far as they are directed to psoriasis. Lilly's other insufficiency objections are rejected.*
> v. *If (contrary to my conclusions) the claims are valid, they have been infringed by Eli Lilly & Co Ltd and Eli Lilly & Co.*

32. Accordingly Arnold J found all the claims of the 822 Patent (as sought to be amended) invalid. Claims 1 and 2 (the antibody product claims), claims 13, 14 and 15 (the first medical use claims) and claims 12, 20 and 22 (the second medical use claims insofar as they related to rheumatoid arthritis ("RA")) were found to be invalid for obviousness over the two groups of prior art, US Patent 344 and publications collectively referred to as the IL-17A/A prior art. Claims 12, 20 and 22, insofar as they related to psoriasis, were found to be invalid being insufficient for lack of plausibility at the priority date of the patent.

33. Lilly produced a table which demonstrates that the Court's findings with respect to the 822 Patent apply equally to the 084 Patent. For convenience this is provided as Annex 1 hereto .

34. The affinity claims, 2 and 15 and the claims more specifically directed to RA and psoriasis, claims 12, 20 and 22, were all new claims sought to be introduced into the 822 Action by way of amendment – in the same way as Genentech now seek to introduce proposed amended claims 9, 10 and 11 in this action.

35. By its application notice dated 28 November 2019, Genentech now seeks permission to introduce the following three new claims into the 084 Patent:

    a. 9. The antagonist anti-IL-17A/F antibody according to any one of claims 1 to 8, wherein said antibody has a Kd for said IL-17A/F polypeptide of at least about $10^{-8}$, $10^{-9}$, $10^{-10}$, $10^{-11}$, or $10^{-12}$ M.

    b. 10. The antagonist anti-IL-17A/F antibody according to any one of claims 1 to 9 for use in the treatment of psoriasis.

    c. 11. The antagonist anti-IL-17A/F antibody according to any one of claims 1 to 9 for use to partially or fully block, inhibit, or neutralize a biological activity of said IL-17A/F polypeptide in the treatment of psoriasis.

36. The affinities of proposed claim 9 are no different to those considered by Arnold J in claims 2 and 15 of the 822 Patent and use for the treatment of psoriasis was the subject matter of claims 12, 20 and 22 of the 822 Patent.

37. The only differences between the 822 Patent and the 084 Patent are the additional features in subsidiary claims 5 and 6 of the 084 Patent, where Lilly submits, the additional integers are inherent features of IL-17A/F: the additional integers of claim 5 are simply to the disulfide bridges that are made when the IL-17A/F heterodimer is formed and the additional integers of claim 6 are no more than the inherent features of IL-17A/F activity. If in fact it be the case that any of the features listed in claim 6 are not inherent biological activities of IL-17A/F, then, Lilly submits, those features must be insufficient. Before me Genentech has not sought to argue otherwise.

38. So far as Genentech's amendment application is concerned Lilly produced a table which shows the correspondence of language and the significance of the findings of Arnold J to the proposed amended claims 9, 10 and 11. For convenience, this is provided separately as Annex 2 hereto .

39. There is no distinction of any patentable significance between the language of the 822 Patent claims as considered by Arnold J and between either of the granted claims of the 084 Patent or the three claims sought to be introduced by amendment and Arnold J's findings apply equally to them all. In Genentech's skeleton argument for this application it is stated that "Genentech will not rely in that regard on claims 1-9 of the 084 Patent containing features not present in the relevant claims of the 822 Patent".

40. So far as claims 10 and 11 of the 084 Patent, the equivalent claims of the 822 Patent were held by Arnold J not to be plausible at the priority date of the patent and were, therefore, invalid. Genentech applied to amend its Defence and Part 20 Claim in the 822 Action to plead that those claims were plausible at the date of filing of the application which was just under 12 months later than the priority date. Arnold J refused that application on case management grounds. Genentech sought to appeal that decision. This was adjourned to the hearing of the substantive appeal in the 822 Action. Floyd LJ gave the reasons as:

> *To the extent that the judge's decision was a case management one, there is no prospect of this court interfering with it. However the applicant may have a valid concern that the judge has decided against them a point of law e.g. the consequences of a finding of implausibility at the priority date. If that this (sic) is still a live issue, the applicants ought to be able to renew their application at the hearing of the main appeal.*

41. In this action Genentech says that its position is that these claims were plausible at the priority date but if I were to find that there was an issue estoppel that prevented it from arguing the point at trial it would defend the plausibility of claims 10 and 11 at the filing date. To that end it seeks permission to rely on an expert report from a Professor Schön of the University Medical Center Göttingen, to establish that it has an arguable case based on the change in the common general knowledge between the priority date and the filing date. Lilly submits that Genentech is estopped from raising this argument in this action on the basis of the doctrine set out in the case of *Henderson v. Henderson* 3 Hare 100 as developed in subsequent cases, particularly *Johnson v Gore Wood & Co* [2002] 2 AC 1. This is often referred to as *Henderson v Henderson* abuse of process.

42. Lilly submits that by its proposed amendments Genentech is seeking to introduce the very same subject matter into the 084 Patent which has been rejected by Arnold J in the 822 Action. Genentech had the opportunity to amend in the 822 Action, they did so, the amended claims were found unallowable and there should be no second bite of the cherry.

43. However, this is the evil that issue estoppel is there to prevent. In so far as the claims are invalidated by issues that were decided in the 822 Action, they will be invalidated in this action if Genentech is estopped from challenging the determination of those issues in this action. If, on the other hand, issue estoppel does not prevent Genentech from raising arguments in this action based on the proposed amended claims then it is not an abuse to make those amendments.

## The Law – General Principles

44. Although the 822 Patent and the 084 Patent are virtually identical, they are different property rights. For this reason, Lilly does not rely on cause of action estoppel but on issue estoppel and *Henderson v Henderson* abuse of process.

45. The underlying public interest in both issue estoppel and *Henderson v Henderson* abuse of process is the same: "*that there should be finality in litigation and that a party should not be twice vexed in the same matter. This public interest is reinforced by the current emphasis on efficiency and economy in the conduct of litigation, in the interests of the parties and the public as a whole.*" Per Lord Bingham of Cornhill in *Johnson v Gore Wood & Co*.

46. A further principle of public policy was succinctly stated by Clarke LJ in *The Good Challenger* [2004] 1 Lloyd's Rep 67 (CA): "*The application of the principles of issue estoppel is subject to the overriding consideration that it must work justice and not injustice."* This followed from Lord Keith of Kinkel in *Arnold v National Westminster Bank* [1991] 2 AC 93 where his Lordship said: "*One of the purposes of estoppel being to work justice between the parties, it is open to courts to recognise that in special circumstances inflexible application of it may have the opposite effect*."

47. The *Arnold* case was concerned with the situation when further material becomes available which could not have been discovered earlier with reasonable diligence. Lilly argue that the special circumstances that may allow derogation from an inflexible application of the principles of issue estoppel are confined to cases where further material becomes available, as in *Arnold*. Lord Sumption JSC, in *Virgin Atlantic Airways Ltd v Zodiac Seats UK Ltd* [2013] UKSC 46, summarised the propositions to be deduced from *Arnold* as:

> *(1) Cause of action estoppel is absolute in relation to all points which had to be and were decided in order to establish the existence or non-existence of a cause of action.*

> *(2) Cause of action estoppel also bars the raising in subsequent proceedings of points essential to the existence or non-existence of a cause of action which were not decided because they were not raised in the earlier proceedings, if they could with reasonable diligence and should in all the circumstances have been raised.*
> *(3) Except in special circumstances where this would cause injustice, issue estoppel bars the raising in subsequent proceedings of points which (i) were not raised in the earlier proceedings or (ii) were raised but unsuccessfully. If the relevant point was not raised, the bar will **usually** be absolute if it could with reasonable diligence and should in all the circumstances have been raised.* (emphasis added)

48. I do not accept Lilly's argument that the special circumstances exception is limited to where further material becomes available. I believe that issue estoppel is subject to being disapplied in circumstances where its strict application would cause injustice. The above quote from Lord Sumption states that even where the relevant point could and should have been raised the bar will only usually be absolute. However, it is only in special circumstances that it will not be applied strictly. Those special circumstances will be where its strict application will cause injustice.

**Issue Estoppel – the Principles**

49. Issue estoppel will only arise where:

    a. An issue has been determined in a final decision in an earlier action between the same parties;
    b. The issue determined in the earlier action must be fundamental to the earlier decision; and,
    c. The issue in the later action is the same as was finally determined in the earlier action.

50. The requirement that the decision in the earlier case must be final does not mean that all avenues of appeal must be exhausted. A decision is a final decision even if it is under appeal as in this case. That is accepted by Genentech in this case. However, Genentech relies on the fact that it has leave to appeal and, following the decision by the TBA to revoke the 822 Patent, the Court of Appeal may not allow that appeal to be pursued. I shall deal with that below under the heading of injustice.

51. There is a difference between the parties as to the meaning of the requirement that the issue must have been fundamental to the decision in the earlier action. I was referred to paragraph 8.23 of *Spencer Bower and Handley*: Res Judicata (5th Edition 2019):

> *"The determination must be fundamental, not collateral. An express decision will not necessarily create an issue estoppel. Only determinations which are necessary for the decision, and fundamental to it, will do so. Other determinations, however positive, do not."*

52. One of the cases referred to in paragraph 8.23 of *Spencer Bower and Handley* is the Australian case of *Blair v Curran* (1939) 62 CLR 464 where Dixon J said:

> *"A judicial determination directly involving an issue of fact or of law disposes once for all of the issue, so that it cannot afterwards be raised between the same parties or their privies. The estoppel covers only those matters which the prior judgment, decree or order necessarily established as the legal foundation or justification of its conclusion, whether that conclusion is that a money sum be recovered or that the doing of an act be commanded or be restrained or that rights be declared.*
>
> *…*

> *"Nothing but what is legally indispensable to the conclusion is thus finally closed or precluded. In matters of fact the issue estopped is confined to those ultimate facts which form the ingredients in the cause of action, that is the title to the right established. … But in neither case is the estoppel confined to the final legal conclusion expressed in the judgment, decree or order. In the phraseology of Coleridge J in R v Inhabitants of the Township of Hartington Middle Quarter (1) the judicial determination concludes, not merely as to the point actually decided, but as to a matter which it was necessary to decide and which was actually decided as the groundwork of the decision itself, though not then directly the point at issue. Matters cardinal to the latter claim or contention cannot be raised if to raise them is necessarily to assert that the former decision was erroneous.*
>
> *…*
>
> *"The difficulty in the actual application of these conceptions is to distinguish the matters fundamental or cardinal to the prior decision of judgment, decree or order or necessarily involved in it as its legal justification or foundation from matters which even though actually raised and decided as being in the circumstances of the case the determining considerations, yet are not in point of law the essential foundation or groundwork of the judgment, decree or order."*

53. To this may be added dicta from two English cases. The first is *Thoday v Thoday* [1964] P 181 where Diplock LJ, as he then was, having described cause of action estoppel, said:

> *"The second species, which I will call 'issue estoppel,' is an extension of the same rule of public policy. There are many causes of action which can only be established by proving that two or more different conditions are fulfilled. Such causes of action involve as many separate issues between the parties as there are conditions to be fulfilled by the plaintiff in order to establish his cause of action; and there may be cases where the fulfilment of an identical condition is a requirement common to two or more different causes of action. If in litigation upon one such cause of action any of such separate issues as to whether a particular condition has been fulfilled is determined by a court of competent jurisdiction, either upon evidence or upon admission by a party to the litigation, neither party can, in subsequent litigation between one another upon any cause of action which depends upon the fulfilment of the identical condition, assert that the condition was fulfilled if the court has in the first litigation determined that it was not, or deny that it was fulfilled if the court in the first litigation determined that it was."*

*54.* The second case is *Arnold v. National Westminster Bank* [1991] 2 AC 93, where Lord Keith said:

> *"Issue estoppel may arise where a particular issue forming a necessary ingredient in a cause of action has been litigated and decided and in subsequent proceedings between the same parties involving a different cause of action to which the same issue is relevant one of the parties seeks to re-open that issue."*

55. Genentech summarises the relevant propositions it derives from the authorities as:

    a. Nothing but what is legally indispensable to the conclusion is precluded by issue estoppel;
    b. In matters of fact, the issue estoppel is confined to those ultimate facts which form the ingredients in the cause of action;
    c. Matters which are subsidiary or collateral do not give rise to an issue estoppel, so that findings which concern only evidentiary facts, and not ultimate facts forming the very title to rights, give rise to no preclusion – however deliberate and formal the findings; and,
    d. Decisions upon matters of law which amount to no more than steps in a process of reasoning do not give rise to an issue of estoppel.

56. I would add a note of caution concerning the adjudication as to what are the fundamental or necessary findings in any particular case and the application of the above identified propositions. Some of the cases involve a Claimant seeking to establish a right or entitlement where it is necessary for it to establish a number of facts and/or points of law. Failure on any one of those issues is fatal to its case. If it does fail on one issue then it would be estopped from asserting the contrary to that one issue in subsequent proceedings. On the other hand, the Defendant would not be estopped from challenging any of the other issues which were established in the Claimant's favour as those issues were not essential to the decision. However, if the Claimant succeeds on all the issues then the Defendant would be estopped in respect of each one of those issues as failure by the Claimant on any one of those issues would be fatal to its case.

57. Genentech relies on the first proposition identified above to submit that there is no issue estoppel where there are alternative grounds for a decision. The reasoning is that where alternative reasons are given for a decision, neither can be said to be necessary or fundamental to the decision reached. This is a very important and far reaching submission, particularly in the field of patents. Patents are frequently challenged on more than one ground. Thus, a patent may be said to be anticipated by some prior art, non-inventive or obvious over another piece of prior art, or to be invalid for insufficiency or added matter. The Judge will determine each ground of invalidity and this will frequently mean that a judgment of invalidity will be made on alternative grounds.

58. I asked Mr Moriarty QC, who addressed me on the issue estoppel aspects of Genentech's submissions whether, it was his case that if a judgment is framed in terms of "I find this patent to be invalid on the ground of X but if I am wrong I would find it invalid on the ground of Y" then issue estoppel would apply to the issues fundamental to ground X but would not apply to the issues fundamental to ground Y. He accepted that would be the case whereas, in a case where the judgment is expressed in terms of "I find this patent to be invalid on each of the grounds, X and Y", there would be no issue estoppel on any of the issues fundamental to either ground.

59. Mr Moriarty referred me to a passage in *Spencer Bower and Handley* at paragraph 8.25 which is headed "No estoppel against successful party on issue he lost". The first paragraph under this heading deals with the subject matter of that heading. The second paragraph states:

> *"The same principle applies where the court finds alternative grounds in favour of the successful party. Those finding do not create issue estoppels because the losing party could not effectively appeal against any of them separately, and if one was upheld the appeal would fail. There may be a cause of action estoppel or merger but no issue estoppel because no single finding could be 'legally indispensable to the conclusion' or the 'essential foundation or groundwork of the judgment, decree or order' as Dixon J said in Blair v Curran".*

60. A footnote to this paragraph refers to the case of *The Good Challenger* [2004] 1 Lloyd's Rep 67 (CA) where Clarke LJ considered the case of a "two ratio" case but concluded he did not need to decide it in the case before him:

> *"70. The Judge was attracted by Mr Turner's submission. He said in par. 48 that it is hard to see why a determination which forms the primary basis of a foreign judgment should not give rise to an estoppel on the issue in question, notwithstanding that the judgment was also reached on an alternative basis. On the other hand there seems to me to be much to be said for Mr. Matthews' submission that the cases support the proposition that the particular determination must be necessary for the decision in the sense of being fundamental to it and that in a two ratio case. Neither can satisfy that test.*

> *71. However that may be, the Judge held that he did not have to determine the question because he held that the decision of the Supreme Court under art. 174(a) was not the (or I think he also meant a) primary basis for the decision. For the reasons given below, I have reached the conclusion that the Judge was correct and that it is not necessary for us to determine the correct approach in a twin ration case. In these circumstances I do not think that I should express a view on the point. There is a good deal to be said on both sides of the question and it seems to me to be preferable to do so only in a case where it arises for decision on the facts.*
> *72. As I see it, assuming that it is possible for each ratio in a two ratio case to give rise to an issue estoppel, the determination of the particular issue relied upon must have been treated by the first Court as necessary for its decision in the sense that it was part of the decision which it in fact reaches and not collateral to it or obiter.*
> *…*
> *"74. In the State of Norway case this Court, having considered the decision of the Privy Council in Duedu v Yiboe [1961] 1 W.L.R. 1040, did not accept that an issue estoppel is impossible if the first decision cannot be appealed. However, it held that it is a good test. It seems to me that the correct approach to the question of appealability is to treat it as one factor in deciding whether the determination is necessary to the decision or only collateral to it."*

## Injustice

61. Mr Moriarty accepted that appealability is not the test but is only one factor in the assessment but he submitted that if an issue could not be appealed then it raised an issue as to whether estoppel on that issue would create an injustice. I suggested to Mr Moriarty QC that the situation might be different where the successful party relied upon issue estoppel in respect of both of the alternative grounds of invalidity, and that in such a case there would be no unfairness or injustice. He accepted that in such a case there would be no unfairness or injustice but he submitted that it was an absolute rule that where there were alternative grounds for a decision there could be no issue estoppel in respect of either ground even if no injustice arose. I do not believe that there is any clear and binding authority to that effect. In my judgment it will depend on all the circumstances of the case.

62. In the present case, Genentech has appealed, as one would expect, the findings of invalidity over both items of prior art. In fact, if the judgment had been in the form "I find this patent to be invalid on the ground of X but if I am wrong I would find it invalid on the ground of Y", it would still be necessary to upset the Judge's findings in respect of both grounds even though the findings concerning ground Y would be obiter. In any event, because Lilly are seeking to rely on the findings of obviousness over both items of prior art I see no injustice in there being issue estoppel in respect of both issues and the issues fundamental to each of them.

63. Mr Michael Tappin QC, who appeared for Genentech together with Mr Stephen Moriarty QC and Mr William Duncan, raised one further ground of unfairness. He pointed out that Genentech had been granted leave to appeal. This, he submitted, was on the basis that they must have a good prospect of success. If I find that issue estoppel prevents them from running the arguments on which they are held to have a good prospect of success on appeal and they are unable to pursue that appeal because the 822 Patent is held never to have existed, this, Mr Tappin says, would create an injustice.

64. I see some force in this argument but at this time this is only a possibility and its potential for causing injustice is outweighed by the certainty that a finding that issue estoppel does not apply would result in a rerun of the lengthy and expensive trial. This cannot be in the public interest and would be an injustice to Lilly. The appeal is still live at the moment and it is in the hands of the Court of Appeal to determine what is in the public interest and the interests of the parties. I cannot make my judgment based on trying to second guess what course of action the Court of Appeal will take. If all the formal requirements for issue estoppel are otherwise

met, I do not see this possibility of injustice justifying me departing from the application of issue estoppel.

65. The underlying public interest referred to by Lord Bingham of Cornhill in *Johnson v Gore Wood & Co*. is a strong factor in this case. The fact that, in the absence of issue estoppel, there would be the prospect of a further trial on exactly the same issues as were determined in the earlier litigation at a combined cost of £11 million suggests that there would be a grave injustice were issue estoppel not to apply here. This case is as close to giving rise to cause of action estoppel as it is possible to get without it applying as all the issues on obviousness are identical in both actions. I find that this is a case where issue estoppel does potentially arise and it is necessary for me to go through each of the pleaded issues to determine whether they are fundamental to the decision.

66. In its Re-Amended Grounds of Invalidity, Lilly identified 43 issues (increased to 44 by adding issue 38A by amendment) which it pleaded as being *res judicata* as regards the 084 Patent and stated "The parties are estopped from relitigating these issues in these proceedings and it would be an abuse to do so."

67. So far as the issue relating to plausibility/sufficiency is concerned, it is accepted by Genentech that this issue, number 43 in the list of issues is fundamental to the decision but Genentech take the point that any issue estoppel in respect of that issue is as to the position at the priority date of the 822 Patent (which is, of course, the same as the priority date of the 084 Patent) but that the relevant date in the present action is pleaded as the filing date. Thus, Genentech says that the issue is not the same in the two actions.

68. Lilly submit that Genentech is estopped from arguing that the issue as to the date at which plausibility is to be assessed is the date of filing and not the priority date. Lilly submits that this is an issue that could and should have been raised in the 822 Action. Lilly relies on *Henderson v Henderson* estoppel/abuse of process.

**Henderson v Henderson Abuse of Process**

69. The principle is engaged when a party seeks to raise in subsequent proceedings not an issue which was raised and decided in previous proceedings, but rather matters which were not raised in the earlier proceedings, but could and should have been.

70. There has always been some degree of flexibility about this doctrine. In *Henderson v Henderson* itself, Wigram VC recognised that the rule preventing a party from raising matters which could and should have been raised in earlier proceedings could always be departed from in special circumstances. That flexibility was referred to in the cases which followed it. It was the decision of the House of Lords in *Johnson v Gore Wood*, however, which emphasised how flexible the doctrine really is. As Lord Bingham of Cornhill said:

> *"The bringing of a claim or the raising of a defence in later proceedings may, without more, amount to abuse if the court is satisfied (the onus being on the party alleging abuse) that the claim or defence should have been raised in the earlier proceedings if it was to be raised at all. I would not accept that it is necessary, before abuse may be found, to identify any additional element such as a collateral attack on a previous decision or some dishonesty, but where those elements are present the later proceedings will be much more obviously abusive, and there will rarely be a finding of abuse unless the later proceeding involves what the court regards as unjust harassment of a party. It is, however, wrong to hold that because a matter could have been raised in earlier proceedings it should have been, so as to render the raising of it in later proceedings necessarily abusive. That is to adopt too dogmatic an approach to what should in my opinion be a broad, merits-based judgment which takes account of the public and private*

> *interests involved and also takes account of all the facts of the case, focusing attention on the crucial question whether, in all the circumstances, a party is misusing or abusing the process of the court by seeking to raise before it the issue which could have been raised before. As one cannot comprehensively list all possible forms of abuse, so one cannot formulate any hard and fast rule to determine whether, on given facts, abuse is to be found or not. … While the result may often be the same, it is my view preferable to ask whether in all the circumstances a party's conduct is an abuse than to ask whether the conduct is an abuse and then, if it is, to ask whether the abuse is excused or justified by special circumstances. Properly applied, and whatever the legitimacy of its descent, the rule has in my view a valuable part to play in protecting the interests of justice*."

71. Thus, the role of the court, when a party seeks to contend that another party cannot raise a point that could have been raised in earlier proceedings, is to make a broad merits-based judgment which takes into account all of the facts, and ask whether, in the light of that, the party alleging abuse has satisfied the court that the other party is misusing or abusing the process of the court by seeking to raise an issue which could have been raised before. Such a finding will be rare unless the later proceedings can properly be characterised as "unjust harassment".

72. One particular context in which this assessment may fall to be made is where a party seeks to raise a matter in subsequent proceedings which it tried to raise in earlier proceedings, but which it was prevented from doing (perhaps because leave to amend to raise the issue was refused in the earlier proceedings). There is little authority on this issue. Such authority as there is, however, goes either way. In *Spencer Bower & Handley*, reference is made to three cases (none of them English).

73. In *Mohammed Kahlil Khan v Mahbub Ali Mian*, [1948] AIR 78, an Indian case, a question arose as to whether a suit to recover certain real property in India was barred by a rule of Indian civil procedure (Order 2, Rule 2) which provided that where a plaintiff omits to sue in respect of, or intentionally relinquishes, any portion of his claim, he shall not afterwards sue in respect of the portion omitted or relinquished. The case is of limited, if any, assistance, because it ultimately turned upon the proper construction of Order 2, Rule 2. As Sir Madhavan Nair said, quoting from another Indian case *"[i]t is the duty of the Courts to interpret and carry into effect those rules uninfluenced by the considerations of the individual loss that may be occasioned by disobedience of the provisions*". It was plainly not applying a broad, merits-based judgment taking account of the public and private interests involved, and asking whether a party was misusing or abusing the process of the court.

74. In *Healthy Living Products International Ltd v Elliott* [2012] HKLRD 49, a Hong Kong case, a company brought proceedings against a defendant to whom it had sold some real property in Hong Kong, seeking a declaration that the sale agreement was invalid and unenforceable for a number of reasons, including that one of the signatories to the agreement (a Madam Chan) lacked mental capacity to enter into the agreement, and that the defendant had exercised undue influence over her. In earlier proceedings in which the purchaser had successfully sued the company for specific performance of the agreement to sell the same property, the company had been refused permission to amend its defence, shortly before trial, to contend that Madam Chan had been the subject of duress and undue influence, and was of unsound mind. Following judgment in that first action, amongst other things the company then applied for a stay of execution, followed by an application for a declaration that the agreement had been validly annulled, both of which were dismissed. After that, another closely related company then commenced proceedings against the purchaser claiming a beneficial interest in the same property, which was struck out as frivolous or vexatious and/or an abuse of the process of court. When, after all this, the defendant purchaser then applied to strike out the

second action as an abuse of process, the Hong Kong Court of Appeal unsurprisingly struck it out. The fact that the earlier court's refusal of permission to amend meant that the issues of undue influence and mental incapacity had not been adjudicated upon was not regarded as a conclusive consideration, but treated rather as a factor in support of the proceedings being an abuse. It is not difficult to see that this was a case where the defendant purchaser was truly being harassed.

75. Finally, in *Macquarie Bank Ltd v National Mutual Life of Australasia Ltd* [1996] 40 NSWLR 543, an Australian case, a bank commenced proceedings against a firm of solicitors claiming damages for their negligence in failing to ensure that certain guarantees and mortgages were valid and enforceable. In earlier proceedings by the bank against the solicitors in which they were claiming damages for the solicitors' negligence in failing to register the transfer of certain insurance policies, the bank had, on the third day of the trial, sought permission to amend to add in a claim for negligence in relation to the guarantees and mortgages, but the trial judge refused permission. When the solicitors contended that the bank was precluded from bringing the second action because, amongst other things, it was an abuse of process, the New South Wales Court of Appeal concluded that it was not. As Powell JA said (with whose judgment on this point Priestly JA and Clarke JA agreed):

> "*It seems to me that, in a case in which a party has sought, but been refused, leave to raise a matter in earlier proceedings, it can hardly be said that through negligence, inadvertence or even accident, he has allowed the point to pass by and ought not thereafter be allowed to seek to raise the matter; rather, as it seems to me, the fact that leave was sought but refused, would constitute special circumstances which would require the Court to permit the matter to be raised in the second proceedings*".

76. *Spencer Bower & Handley*, at paragraph 8.36, prefer the view that the *Henderson v Henderson* principle applies if permission to raise an issue was refused, and summarily assert that *"[t]he contrary view of Powell JA … cannot be accepted*". There is much to be said for the point that, if a party has been refused permission to raise a point in earlier proceedings for case management reasons which do not apply in the later proceedings, the fact that permission was refused in the earlier proceedings should not inherently prevent the point being raised in the later proceedings. On any view, moreover, it cannot override the broad merits-based judgment mandated by *Johnson v Gore Wood*, and is at most one factor to be taken into consideration in the overall assessment.

77. In the 822 Action, Lilly pleaded that the patent was invalid as the claims relating to psoriasis were not plausible at the priority date of the patent. Genentech pleaded that the claims were plausible but did not challenge the date at which plausibility was to be assessed. As referred to above Genentech did apply in that action to amend to plead the later date but that amendment was not allowed by Arnold J on the ground, inter alia, that the amendment was sought too near the trial date. He refused the application on case management grounds. Genentech applied to the Court of Appeal for permission to appeal and that was adjourned to be heard, if appropriate, at the hearing of the substantive appeal. If the substantive appeal does not go ahead then this appeal will not go ahead either.

78. Genentech say that they have pleaded plausibility at the date of filing in this action at the appropriate stage of the pleadings, in their Amended Defence and Counterclaim served on 13 November 2019, and that there is no estoppel to prevent them relying on that date to defend the 084 Patent.

79. Lilly now say that there is *Henderson v Henderson* estoppel in that the lateness of Genentech's application to amend to plead the different date in the 822 Action was of their own making

and Lilly points to the delay in applying to amend in the 822 Action after it should have become apparent to Genentech that it needed to amend if it wanted to rely on common general knowledge at the date of filing. The timetable relied upon by Lilly is:

- **3 July 2017** - 822 Action commenced by Lilly and Claim Form served.
- **21 December 2017 -** Lilly serve Amended Grounds of Invalidity with no challenge to priority and pleads its arguments on lack of plausibility
- **5 January 2018** - Genentech's Defence and Counterclaim served with no alternative plea to plausibility at filing date. Although there were further amendments to the statements of case subsequent to this in **July** and **December 2018**, Genentech does not touch on the question of plausibility at the filing date at that stage either.
- **7 November 2018** - Evidence in chief exchanged. This included evidence from Genentech's psoriasis expert, Professor Errol Prens and Lilly's psoriasis expert, Professor James Krueger. Both experts addressed: (i) the common general knowledge of the skilled dermatologist and (ii) the issue of whether the treatment of psoriasis by the claimed antibodies was plausible, both as of the priority date, being 8 July 2003.
- **4 December 2018** (6 weeks before trial) – Genentech, by letter, puts Lilly on notice (for the first time) that they would seek to advance a contingent defence that, if Lilly succeeded on its allegation of lack of plausibility regarding the treatment of psoriasis, then Genentech would contend that, so far as psoriasis was concerned, they would argue that plausibility should be considered as of the filing date, 2 June 2004.
- **11 December 2018** - reply evidence exchanged from both Prof Krueger for Lilly and Prof Prens for Genentech. No evidence served by Genentech to support their alternative case.
- **20 December 2018** – The hearing of Genentech's application to amend its Defence and Counterclaim to introduce its contingent defence. Lilly contests its introduction on the basis that this late amendment would materially prejudice Lilly and that it was not supported by Genentech's evidence.

  The Judge refused Genentech's application. The Judge held that neither Genentech's psoriasis expert, Professor Prens, nor Lilly's psoriasis expert, Professor Krueger, supported the alternative case that Genentech wished to introduce. He also notes additional reasons that supported his decision – all predicated on the failure of Genentech to raise the contingent defence and bring the amendment earlier - being: (i) the lateness of Genentech's application, (ii) the failure of Genentech to advance the alternative case prior to the service of expert evidence, (iii) a lack of any proper explanation for the delay from 7 November 2019 to 4 December 2019 and (iv) the fact that it was only a short period away from the commencement of the trial with the Christmas and New Year period intervening.
- **16 January 2019** - trial commences and lasts for 14 days.
- **1 March 2019** – Judgment handed down.

80. It is clear from this that Genentech could have raised the issue of the relevant date at an earlier stage of the 822 Action and that would have been likely to have been allowed. The question is whether they should have raised the issue in the 822 Action and whether not having done so it would be an abuse for them to do so now.

81. Lilly makes two points, namely:

1) Had Genentech wanted to run this alternative they could and should have done so in the 822 Action. It is plainly an issue which properly belonged to the 822 Action and is issue estopped accordingly: *Spencer Bower and Handley* at para.8.36. The fact that Genentech did not raise this point in the 822 Action until it was too late to do so does not displace this fact; and

2) Even if the point was open to be run, Genentech has not put before the Court any evidence that overcomes the reasons given by Arnold J for finding a lack of plausibility as summarised in [577] of his judgment. These reasons turn on the lack of disclosure of the Patent in the light of the judgment of the Supreme Court in *Warner Lambert Co. v Generics UK Ltd* [2018] UKSC 56 (see Arnold J at [523] to [531] and the assessment of Lord Sumption's factors by Lilly's expert quoted by Arnold J at [562]). The belated attempt to adduce a new report from Professor Schön manifestly does not do so.

82. Dealing with the first of Lilly's points and taking a broad merits based assessment, I do not believe that Genentech should be shut out from arguing plausibility at the filing date simply because they could have pleaded this case in the 822 Action and left it too late to seek to amend to include that argument. Lilly have a further argument, namely that Genentech could have obtained grant of the 084 Patent in time for it to have been included on the 822 Action. They set out the timeline for the prosecution of the 084 Patent. I have included within this timeline the revocation of the 822 Patent by the Opposition Division (OD) which was upheld by the TBA in January of this year and the start of the trial and the handing down of the judgment in the 822 Action:

- **01/10/2014**: Publication of the European search report and accompanying opinion. 6 months given for response.
- **12/05/2015**: Application deemed to be withdrawn (failure to respond to Written Opinion).
- **21/07/2015**: Genentech respond to Written Opinion and attach amended claims.
- **30/07/2015**: Examining Division (ED) decision to allow further processing.
- **12/10/2016**: Opposition Division revoke 822 Patent
- **31/10/2016**: Examination started.
- **09/11/2016**: ED communication that application doesn't meet EPC requirements. 4 months given to amend.
- **09/03/2017**: Genentech request extension of time limit.
- **15/03/2017**: ED grant 2 month extension.
- **19/06/2017**: Time limit expires; application deemed to be withdrawn. Genentech has 2 months to request further processing.
- **24/08/2017**: Genentech request further processing and attach amended claims.
- **08/09/2017**: ED decision to allow further processing.
- **07/12/2017**: ED communication that application doesn't meet EPC requirements. 4 months given to amend.
- **10/04/2018**: Genentech request of extension of time limit.
- **13/04/2018**: ED grant 2 month extension.
- **16/07/2018**: Time limit expires; application deemed to be withdrawn. Genentech has 2 months to request further processing.
- **24/09/2018**: Genentech request further processing and attach amended claims.
- **04/10/2018**: ED decision to allow further processing.

- **07/02/2019**: ED consultation report (based on telephone call held 01/02/2019): main request submitted 24/09/2018 appears to meet EPC requirements. Request for amended description with 2 months to do so.
- **16/01/2019**: Start of the trial in the 822 Action.
- **08/02/2019**: Genentech send amended description.
- **01/03/2019**: Judgment of Arnold J in 822 Action handed down.
- **18/03/2019**: Final text intended for grant submitted.
- **27/06/2019**: ED decision to grant application based on 18/03/2019 documents.
- **24/07/2019**: Date of grant of Divisional Patent.
- **27/08/2019**: 084 Action commenced.

83. There is no doubt that this timeline shows a very dilatory approach to the prosecution of the 084 Patent but nevertheless, it was within the rules of the EPO. Lilly points out that it is in Genentech's interest to prolong the life of 084 Patent as much as they can in order to disrupt Lilly's marketing of its Taltz® product. If that was the agenda behind the dilatory prosecution of the 084 Patent, that might well amount to harassment. However, the timeline alone is not enough to establish such an intention and I am not prepared to infer it from the evidence before me. Again, I do not accept that Genentech should be shut out from arguing plausibility at the filing date.

84. Dealing with the second of Lilly's points, I find that it is arguable that the effect of a finding of lack of plausibility at the priority date will only result in a loss of priority if plausibility can be established at the filing date.

85. I also find that Professor Schön's evidence, which I allow in, establishes an arguable case that there was a change in the common general knowledge between the priority date and the date of filing, particularly as shown by the *Lee et al.* 2004 paper such that plausibility could be established at the filing date. Professor Schön's evidence was criticised by Lilly because it approached the issue of plausibility from scratch rather than starting from the findings of Arnold J as at the priority date and identifying the relevant development of common general knowledge between that date and the filing date. I find that to be a valid criticism but even ignoring those parts of his evidence relating to the common general knowledge as at the priority date I find that his evidence has, as I have said, established an arguable case of plausibility at the filing date.

86. Lilly argued that Arnold J's assessment was based on the disclosure (or lack of it) in the 822 Patent and that, therefore, no evidence could upset that assessment. However, I accept Genentech's submission that the Judge's assessment of the disclosure in the 822 Patent was, as it had to be, in the light of the common general knowledge and that developments in the common general knowledge could change the assessment of the disclosure in the 822 Patent.

87. A document showing the issues alleged by Lilly to be the subject of issue estoppel is attached as Annex 3. This is an extract from paragraph 5 of Lilly's Re-Amended Grounds of Invalidity and it shows those issues which Lilly says are not actually the subject of Genentech's appeal highlighted in yellow. Lilly seeks to make two amendments to this list one of which, the insertion of issue 38A, is consented to by Genentech and the other is opposed.

88. The amendment that was opposed is the insertion of "for the reasons given by Prof Krueger" before [577] at the end of issue 40. Mr Andrew Waugh QC, who appeared for Lilly together with Mr Jeffrey Chapman QC and Dr Stuart Baran told me that Genentech's objection is that

it is not clear from the judgment what the reasons were. As a result, Lilly sought to add in a reference to paragraphs [553] and [557] to [562] to identify the reasons referred to. Mr Tappin maintained the objection to the amendment to issue 40 and to issue 40 in its entirety on the basis that it still wasn't clear and that it misrepresented the Judge's findings by the inclusion in the statement of the issue of the words "… in the light of the specification …". This, Mr Tappin submitted, was seeking to remove the common general knowledge and, in particular, the papers which had been published and which the Judge relied on in considering the relevant common general knowledge. I shall allow these amendments to the list of issues in paragraph 5 (a) of the Re-Amended Grounds of Invalidity but I shall add in to issues 40, 41 and 43 the words "at the priority date of the patent".

89. Genentech submits that the fact that they have not specifically appealed the majority of the identified issues shows that those issues are not fundamental to the decision and so should not be the subject of issue estoppel. I do not accept that that is a reliable test as to what issues are fundamental. There may be a number of fundamental issues, any one of which if challenged successfully would overturn the decision.

90. Issues 19, 20, 21, 23, 38, 38A and 39 in Lilly's list are the actual findings by Arnold J of obviousness over the prior art and are legally indispensable to the conclusion of invalidity of claims 1, 2, 13, 14 and 15 and claims 12, 20 and 22 in so far as those claims are directed to rheumatoid arthritis. I find that these issues are the subject of issue estoppel. The only basis on which these can be argued not to be legally indispensable to the conclusion of invalidity is that they include alternative grounds. As I have indicated above, I believe that this is not an answer to issue estoppel as Lilly rely on both grounds and that avoids any injustice.

91. The following issues are not the actual findings of obviousness but are the groundwork for those decisions and accordingly I find them also to be the subject of issue estoppel:

    a. Issues 1 to 5 inclusive identify the skilled addressees of the Patent;

    b. Issues 6 to 11 identify the common general knowledge;

    c. Issues 12 to 18 identify what the skilled addressees would understand from the Patent and the US344 prior art;

    d. Issues 24 to 27 identify what the skilled addressees would have done in following the IL-17A/A prior art;

    e. Issues 28 to 33 identify further work that the skilled addressee would have done in following the IL-17A/A prior art;

    f. Issues 34 to 38 identify the likelihood that antibodies produced by the skilled addressees following the IL-17A/A prior art would exhibit the characteristics required by the conditional amendments to claims 13, 14 and 20 of the 822 Patent;

92. Issue 43 is the actual decision that claims 12, 20 and 22 of the 822 Patent are insufficient for lack of plausibility in so far as they are directed to psoriasis at the priority date and is the subject of issue estoppel. Issues 40 to 42 are the groundwork for that decision and I find that they too are the subject of issue estoppel but they also apply only at the priority date.

## Summary Judgment

93. On the basis of my findings on the preliminary issue I conclude that the Defendant is estopped from arguing that claims 1 to 8 inclusive of European Patent (UK) No 2784084 and claim 9 as proposed, are valid and that I therefore find such claims invalid.

94. I further conclude that the Defendant is estopped from arguing that claims 10 and 11 as proposed to be inserted by amendment of European Patent (UK) No 2784084 were plausible at the priority date of the said patent.

95. I conclude that the Defendant has a real prospect of defending the claim that claims 10 and 11 as proposed were plausible at the filing date of the said patent, 2nd June 2004, on the basis that the common general knowledge had developed sufficiently between the priority date of the said patent and the 2nd June 2004 and therefore refuse summary judgment in respect of those claims. I will stand the application to amend the patent to the trial of the action.