[2012] EWPCC 33

Case No: CC11P01399
HC11C01398

IN THE PATENTS COUNTY COURT

Rolls Building
7 Rolls Buildings
London EC4A 1NL

Date: 26/07/2012

**Before** :

**HIS HONOUR JUDGE BIRSS QC**

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

**Between :**

| | |
|---|---|
| **BARRY LIVERSIDGE** | **Claimant** |
| **- and -** | |
| **(1) OWEN MUMFORD LIMITED** | |
| **(2) ABBOTT LABORATORIES LIMITED** | **Defendants** |

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

**James Abrahams** (instructed by **Field Fisher Waterhouse LLP**) for the **Claimant**
**Anna Edwards-Stuart** (instructed by **Manches LLP**) for the **First Defendant**
**Daniel Alexander QC and Charlotte May** (instructed by **Herbert Smith LLP**) for the **Second Defendant**

Hearing dates: 28th, 29th June 2012

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

# 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.

.....

HIS HONOUR JUDGE BIRSS QC

## His Honour Judge Birss QC:

Contents:



*Introduction*

1. The action is for infringement of European Patent (UK) 2 067 496 entitled "Medical Injector". It has a priority date of 3 February 2003. The Patent is owned by the Claimant, Mr Liversidge. He contends that the Patent is infringed by the Humira Pen, which is an automatic medical injection device manufactured and supplied by the defendants. The defendants deny infringement and counterclaim for invalidity.

*The history of these proceedings*

2. Mr Liversidge has invented a number of products over the years. One was a safety arrangement for a medical needle. He filed a patent application for it in June 2003 claiming priority from 3 February 2003. The design was for a syringe which had no automatic injection capability. It was for a normal (non-autoinjector) syringe and all of the disclosure and claims related to the safety arrangement. The safety arrangement had nothing to do with the "sequencing" requirement which now features large in this case.

3. Humira is one of the world's best selling drugs. It is used to treat rheumatoid arthritis. In 2006, Abbott launched the Humira Pen in the UK – an autoinjector delivery version containing the Humira drug. The pen injector product itself was designed by Owen Mumford. One of the designers of the pen injector was Steven Rolfe, then an employee of Owen Mumford.

4. In March 2009, some 6 years after the original patent application, Mr Liversidge filed a divisional application. That is the application which matured into the patent in this case. Abbott contended that it was filed having seen the success of the Abbott Humira product. Mr Liversidge did not suggest otherwise. The divisional application cut out almost all of the original application apart from one part of the disclosure relating to one of the embodiments which had "protuberances". New text was also introduced by way of characterisation of the prior art describing the "sequencing

problem". One of the issues arising in this case is an allegation that these changes create a problem of added matter.

5. Mr Liversidge tried to interest the defendants in taking a licence under the patent. They did not. On the day the patent was granted (27th April 2011) each side started proceedings. Mr Liversidge sued for infringement in the Patents County Court and Abbott sued for revocation in the High Court. At an early stage in the proceedings the parties agreed terms on which the case would be heard in the Patents County Court (see the judgment arising from the CMC [2011] EWPCC 34).

6. Mr Liversidge contends that the Humira Pen infringes the patent. He relies on the expert evidence of Mr Rolfe. One of the major issues in the case is the question of how the Humira Pen works. Since Mr Rolfe designed it, he is in a good position to explain how it works. If Mr Rolfe's view about the Humira Pen is accepted, then the product will infringe Mr Liversidge's patent.

7. The defendants deny infringement. They argue that despite Mr Rolfe's view about how the Humira Pen he designed was intended to work, in fact the product does not work that way. The defendants called evidence from Martin Murphy. He is a consulting engineer. Mr Murphy conducted experiments to see how the Humira Pen works. His opinion is that the Pen works in a different way from the manner alleged by Mr Rolfe. These rival opinions and the experimental and other evidence will need to be considered to decide the issue of infringement.

8. The defendants also contend that the patent is invalid. It is said to lack novelty over two citations: US 3,742,948 ("Post") and US 3,797,489 ("Sarnoff"). There is also the added matter objection and a point on insufficiency.

9. Directions were given at the CMC limiting the expert evidence to certain issues and confining the evidence of fact to a point about another injector pen called the Epi-Pen. There was no order for disclosure. The trial was heard on 28th and 29th June. The first day consisted of a very brief opening, followed by the cross-examination of the two expert witnesses. With some gentle encouragement from the court, the parties kept to the time allocated for cross-examination. The second day was devoted to oral submissions.

10. At the trial James Abrahams appeared for Mr Liversidge instructed by Field Fisher Waterhouse. Anna Edwards-Stuart appeared for Owen Mumford, the first defendant instructed by Manches. Daniel Alexander QC and Charlotte May appeared for Abbott instructed by Herbert Smith. On the defendants' side the main submissions were made by Mr Alexander.

11. 10 days before trial Mr Liversidge served a third expert's report from Mr Rolfe. This dealt with two points. In paragraph 3 Mr Rolfe explained a point of detail he had recently observed in the videos of Mr Murphy's experiments attached as Annex C to the second defendant's Defence and Counterclaim. In paragraph 4 Mr Rolfe stated that he had taken apart an unused Humira Pen, performed a simple manual test on the parts and that the results of that test provided further confirmation for the opinions he had expressed in his second report.

12. The defendants objected to Mr Rolfe's third report. I decided to admit paragraph 3 but not paragraph 4, with reasons to be given in this judgment. My reasons are as follows:

    i) Pursuant to CPR r63.23(2), only in exceptional cases will the Patents County Court admit material into the proceedings which was not permitted by an order made at the case management conference. In considering whether to admit material in this way the court will always consider the risk of prejudice to the other party and the overall balance of justice. The hurdle set by CPR r63.23(2) is and is intended to be more difficult to satisfy than the general position under the CPR. This higher hurdle is an important part of the overall package of rules in the PCC designed to streamline the conduct of intellectual property litigation.

    ii) The CMC order in this case did not permit this evidence.

    iii) The evidence in paragraph 3 represents an observation which could always have been made. It could have been made at trial. Further, the defendants accepted that Mr Rolfe's observation was correct at least to some degree. There will be a debate about the conclusions to be drawn from it but that is a matter which can be explored in the cross-examination, which was already provided for in the CMC order. The defendants are not seriously prejudiced by this point being raised in this way. The videos are of the tests conducted by the second defendant and annexed to its Defence and Counterclaim. I will admit paragraph 3 despite its lateness and the fact it is outside the order for directions.

    iv) The position vis a vis paragraph 4 is different. It is a new test. Although it is superficially simple, it is in fact an experiment and should always have been the subject of a notice. Mr Liversidge suggested it arose from a recent observation that the syringe barrel in the Humira pen is flared. That may be so but it does not alter the nature of the evidence now sought to be admitted. To investigate the matter properly a sample of pens would need to be tested. That has not been done. To admit this evidence would prejudice the defendants since it is not realistic to expect further tests in reply to be performed. On the other hand the argument which this test is intended to support is a point Mr Liversidge is going to run anyway. Mr Liversidge is not seriously prejudiced by not admitting this evidence.

    v) I doubt this evidence would be admitted in these circumstances into a patent case proceeding in the High Court. It certainly ought not to be admitted in the Patents County Court.

## The witnesses

13. Mr Liversidge called Mr Rolfe. He has an undergraduate degree in Industrial Design Engineering and a Masters in Industrial Design. He has extensive experience of designing medical injection devices of the type in issue. He worked for 12 years at Owen Mumford as an industrial designer. While at Owen Mumford he was part of the team that designed and developed the Humira Pen shortly after the priority date.

14. The defendants called Mr Murphy. He has an undergraduate degree in Mechanical Engineering and is a Chartered Engineer. He works as a consulting engineer in a broad field which includes medical devices, including medical injectors. Mr Murphy accepted Mr Rolfe had more knowledge of injector products on the market than he did.

15. Having heard both witnesses, I thought both of them gave their honest, genuinely held views. In closing the defendants suggested Mr Rolfe was not "genuinely independent". If the submission was intended to be a suggestion of partiality by Mr Rolfe as a witnesses then I reject it. First and primarily because I detected no such bias in Mr Rolfe's testimony. Second, it is not fair to the witness to take that point without putting it to him in cross-examination. In the Patents County Court cross-examination is time limited. Necessarily therefore, in the PCC, there is no need to put the whole of a party's case to the witnesses in cross-examination. The time allowed for cross-examination in the PCC procedure is intended to allow a party to put the major points which need to be addressed in cross-examination to the relevant witnesses. In this case there was ample time for that and if an expert is to be alleged to be biased, that should have been put.

16. I think what the defendants intended in referring to Mr Rolfe's independence was to emphasise that Mr Rolfe had designed the Humira Pen and therefore approached its operation from that stand point. I think there is force in that point. I thought Mr Rolfe was in a difficult position and found it hard to accept that the experiments at face value show the device working in a different manner from the way he intended.

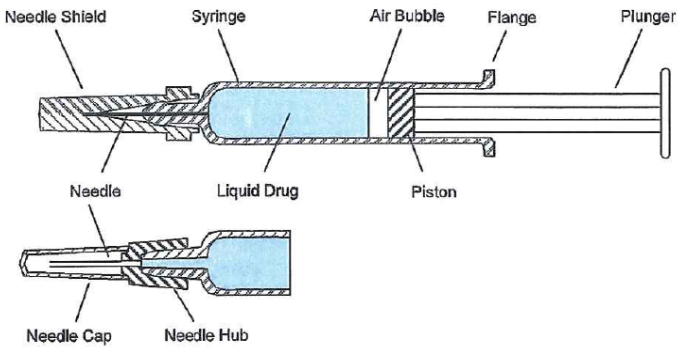
17. There is also a witness statement from Mr Jennings relating to the design of the Epi-Pen. Its relevance to the dispute is marginal.

*The skilled person*

18. The characteristics of the skilled person were common ground. The patent is directed to an individual or team with product design and product engineering expertise, working in the medical devices field with a particular interest in the design development and manufacture of injectable drug delivery devices. They would work for a company like Owen Mumford or one of the consulting firms with experience in this area. In 2003 the product engineering and product design roles for the design and development of an injectable delivery device would probably have been carried out by different people. Product engineering and product design are separate but overlapping disciplines. A product engineer will usually be a mechanical engineer who has knowledge of the principles of physics and mechanics to design and manufacture a viable device. The individual may or may not have undergraduate and postgraduate qualifications, but he would certainly have a number of years of practical experience from working for a medical device company like Owen Mumford or a product development company servicing the medical industry. A product designer, however will have knowledge of ergonomics, user interactions, usability, aesthetics and styling of medical devices. It is possible that both sets of skills would be combined in one individual.

*Common general knowledge*

19. The basic components of a medical injector are usefully illustrated by a diagram taken from Mr Murphy's expert report.




20. The diagram needs no introduction. Sometimes in the documents in this case the part called the piston in the diagram is referred to as the "plunger" and the part called the plunger in the diagram is referred to as the "plunger rod". In this judgment I will use the terminology as it appears in the diagram.

21. In use there are or should be two steps: first, the needle should be inserted to the correct depth within the patient's body; second, the medicament is expelled from the device into the patient's body. This is called sequencing. Sequencing errors can cause so called "wet injection", when medicament is expelled on a patient's skin and can cause the medicament to be delivered at the incorrect depth. Neither is desirable.

22. It is not accurate to say that the "sequencing problem" was common general knowledge. The need to ensure proper sequencing was firmly part of the common general knowledge but it was not an unsolved problem. It had been solved. Those skilled in the art knew that sequencing had to be achieved and knew ways of achieving it. An alternative or better way of ensuring sequencing would always be of interest.

23. In addition to the sort of simple device shown in the diagram above, there are devices called auto-injectors. In these devices, the plunger is pushed forward by means of a firing spring. The firing spring is activated by the user somehow (e.g. pressing a button). The Humira Pen is an auto-injector.

24. Another element of common general knowledge is stiction. When a body is at rest, such as a rubber piston inside the glass barrel of a syringe, a certain degree of force is required in order to push it forwards and start it moving. The force at this stage has to overcome the static friction or "stiction". Very often that force is larger than the force needed simply to push the body forwards once it is moving. In other words dynamic friction is often less than stiction.

25. The question of ensuring proper sequencing is really an issue with auto-injector products. Many well known auto-injector devices used stiction as a way of addressing sequencing. As the plunger is pushed against the piston, the force is not sufficient to overcome stiction and as a result the syringe body as a whole moves forwards. The piston remains stuck in the same place in the syringe. Then when the syringe can go no further, the driving force overcomes the stiction and the plunger starts to push the piston down inside the syringe, expelling the drug.

26. Another aspect of common general knowledge, which the defendants emphasised, were the basic engineering skills of CAD design and prototyping as well as knowledge of plastic materials and plastic moulding techniques. There was no dispute about this.

*The patent*

27. The patent starts by explaining that the invention relates to a mechanism for performing injections. There is then a section discussing the prior art. At paragraph [0004] the document refers to the need for a correct sequence of events in order to perform an injection. It states that this required sequence has been attained by various prior art devices. Paragraph [0005] describes a prior art auto-injector mechanism. The word "auto-injector" is not used but the text refers to a mechanism which is arranged selectively to drive the syringe and needle to penetrate the body and then to apply a force to the plunger to expel the drug. That must be an auto-injector.

28. Paragraphs [0006] to [0012] continue discussion of the prior art and the matter of sequencing. At paragraph [0013] the document states that "as is clear from the wealth of prior art, there is a continuing need for a mechanism for performing an injection that is able to achieve proper sequencing…".

29. The consistory clause which corresponds to claim 1 comes next. A key aspect of the invention is the use of protuberances on the plunger. These are to engage with the rear of the syringe so that the plunger pushes the syringe (and needle) forward. Once the needle has reached the correct depth, extra force is needed to squeeze the protuberances inside the barrel of the syringe so that now the plunger pushes the piston forwards inside the syringe and expels the drug into the body. At paragraph [0015] the patent explains that the invention allows the proper sequencing of an injection and states that "thus the protuberances on the plunger enable the medical injector automatically to sequence a successful injection." There was a debate before me as to whether this was a reference to an auto-injector system. Read in the context of the document as a whole up to that point, the skilled reader would understand this to be referring to an auto-injector arrangement.

30. Paragraph [0016] explains that the plunger may have an X-shaped cross-section and the document then moves on to describe a particular exemplary embodiment in figures 1A to 1J. Figure 1B is as follows:

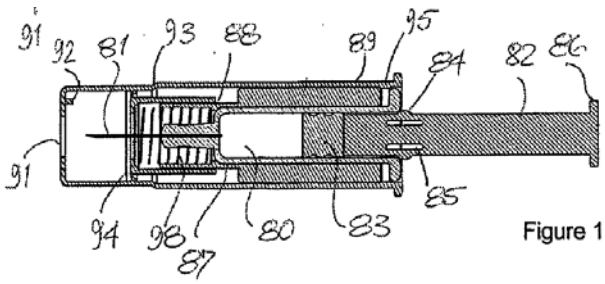



Figure 1B

31. This shows the starting position of the device. There is a sleeve 89 and a syringe with a body 80. The plunger is item 82, the protuberances are items 84 and the piston is item 83. There are slots in the plunger marked as item 85 which allow the protuberances to flex inwards. With the protuberances outside the syringe, the effect

of pushing on the plunger is to push the syringe to the left by the action of the protuberances bearing on the back of the syringe. A momentarily increased force pops the protuberances inside the syringe body and allows the plunger to push the piston and push out the drug – as show in fig 1F below:

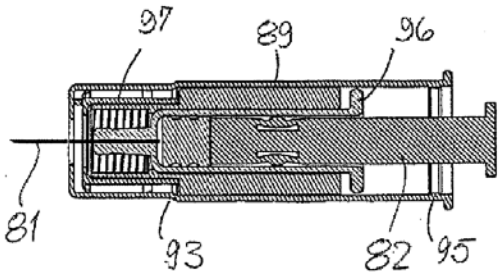



Figure 1F

32. The device has a safety arrangement so that once the injection is finished and when the needle is pulled out of the body, the spring 98 keeps the blocking member 97 pushed against the left hand end of the assembly (actually against a small part called "upstand 92" – see fig 1B). Meanwhile the needle retracts. Once the needle has retracted fully the spring force causes the blocking member to cant sideways and block the assembly, preventing the needle from being pushed forward and out again. This is shown in Fig 1G:

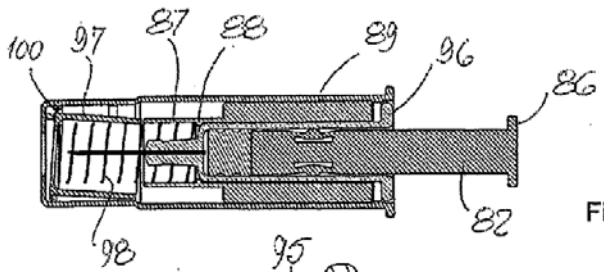



Figure 1G

*Construction and the claims*

33. The legal approach to patent construction is well established and there was no dispute on it before me. The leading authority is *Kirin Amgen v TKT* [2005] RPC 9. The key point is that construction is concerned with what a skilled person would understand the author to be using the words to mean. Guidelines on the general approach were given by the Court of Appeal in *Virgin Atlantic v Premium Aircraft* [2010] FSR 10. I remind myself that claims are not construed alone or in the abstract but in their context in the specification; that purposive construction is vital (there may be several purposes and several embodiments) and that one is in the end concerned with the meaning of the language used. Meticulous verbal analysis is eschewed.

34. The relevant claims are claims 1 and 3. Claim 1 is set out below divided into integers:

Claim 1

[1A] *A mechanism for performing an injection,*

[1B] *the mechanism comprising a syringe,*

[1C] *a plunger (82)*

[1D] *and a sleeve (89),*

*wherein:*

[1E] *the syringe has a needle (81) with a sharp tip at the forward end thereof, and the body (80) of the syringe has a bore housing a piston (83) so that a medicament contained within the syringe can be expelled through the needle (81) by moving the piston; and*

[1F] *the syringe is disposed within the sleeve (89), which has a forward end (89A) and is slideable rearwardly relative to the syringe to allow the needle of the syringe to project from said forward end;*

*characterised in that:*

[1G] *said plunger (82) is provided with protuberances (84) disposed partway along the length thereof,*

[1H] *and in the region of the protuberances the plunger has a through-slot (85) to enable radially inward movement of the protuberances,*

[1I] *so that the protuberances (84) define a stop position for the plunger on being moved into the bore by the application of axial pressure to the remote end (86) of the plunger,*

[1J] *whereby when the protuberances are about to enter the rear end (96) of the syringe body, said pressure moves the syringe relative to the sleeve (89) to cause the needle to project from the forward end (89A) of the sleeve,*

[1K] *and an increase in force is then momentarily required to move the plunger deeper into the syringe body,*

[1L] *thus moving the piston and expelling the medicament from within the syringe.*

35. Thus the claim requires that the plunger has "protuberances". This is not a term of art. One dictionary definition of "protuberance" is a bulge out or a swelling. In my judgment the skilled person would not regard this word as having been used in order to distinguish between different kinds of bulges or other features protruding from the plunger. The point of the protuberances is to protrude outwards so as to bear on the rear of the syringe and to be able to bend inwards to allow the plunger to move further into the syringe to push the drug out.

36. There is a point on "partway" in feature 1G. The protuberances must be disposed partway along the length of the plunger. The skilled reader would understand this to indicate that it did not matter much where along the length of the plunger the protuberances had to be. This feature becomes important in relation to the prior art and I will address further points on construction in that context.

37. An argument on construction was concerned with "through-slot" in feature 1H. It is not a term of art. A slot is simply a groove or channel of some sort. In the figures of the patent it can be seen that the through-slots 85 are all the way through the wall of the plunger material. They run "through" from one side of the protuberance to the other. The point of the through-slot is to allow the protuberances to flex inwards. If the slot was not a through-slot, there would be a web of material behind the protuberance which would stop it flexing inwards.

38. Mr Liversidge contended that a "through slot" had to be bounded on all sides (as shown in the figure 1B above). The defendants contended that a "through slot" could be open at one end (consider figure 1B but imagine the right hand end of the protuberance was not connected to the wall of the plunger). The purpose of this argument was to avoid the prior art. I reject Mr Liversidge's construction. In my judgment the wording would not be understood that way. There is nothing in the words used which require the through-slot to be bounded on all sides.

39. Although it is convenient to divide the claim into integers, it is sometimes important to read them together. The claim is to a product. The product is a mechanism with certain constructional features (syringe, plunger, protuberances etc.) but there is more to the claim than that. Features 1G to 1L together create functional limitations. Language like "so that" (feature 1I) and "whereby" (feature 1J) indicate that the mechanism is also defined by the way the features work and interact. That is significant because one way in which Mr Liversidge's infringement case is advanced is as follows. The presence of obvious constructional features like syringe, plunger etc. are admitted. Mr Liversidge contends that if he can show that the Humira Pen has protuberances partway along the plunger, through slots and so on, then since the claim is a product claim, the product must infringe and it does not matter how the product behaves in practice. I reject that argument on the facts of this case. This product claim requires the mechanism to behave in a particular way. It is not enough to point to protuberances etc.. In order to satisfy this claim, the features must interact and behave in the manner required by the claim. An obvious example is the through-slot. A device with a through slot which was too stiff to allow radial inward movement of the protuberances would not satisfy the claim even though it had a "through-slot".

40. A key functional feature is set out in features 1I and 1J. Feature 1J provides that when the protuberances are at the rear of the syringe "said pressure" moves the syringe and causes the needle to project forward. As a matter of language "said pressure" refers back to the axial pressure applied to the rear of the plunger mentioned in feature 1I. It was common ground that although the claim does not recite in words that the protuberances must engage with or push on the syringe, nevertheless this part of the claim would be understood to mean that the protuberances deliver "said pressure" to the rear of the syringe. The "stop position" referred to in feature 1I is the position when the protuberances are engaged with the rear of the syringe to push it.

41. A question arising on this point is the degree to which the patent would be understood as allowing for the transfer of axial pressure to be via stiction (by the plunger pushing on the piston) as opposed to by the direct transfer of force from the protuberances to the rear of the syringe. It was pointed out that as drawn the plunger is touching the piston and so Mr Liversidge argued that the skilled person would understand that some stiction could be employed to move the syringe in addition to engagement.

42. The disclosure makes no mention of stiction and the text never states that the plunger bears on the piston at the point the protuberances are bearing on the rear of the syringe. Although it is drawn that way in some figures (e.g. fig 1B), if anything to my eye the clearest drawing, Figure 1H, shows the plunger bearing on the piston before the protuberances touch the rear of the syringe:

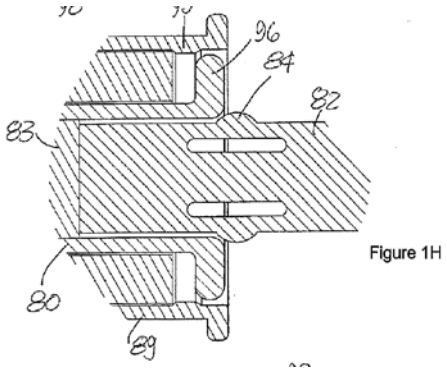


Figure 1H

43. Thus figure 1H might suggest that the piston has to move a little (and therefore stiction overcome) before the protuberances can engage with the rear of the syringe.

44. Patents are to be read purposively. I think a fair reading of the document and figures as a whole is that the point of the protuberances is to engage with the rear of the syringe in order to push it and then to squeeze inwards and let the plunger push out the drug. The skilled reader would understand that this is how the device is supposed to work. No doubt if a small amount of stiction is involved then that would not be regarded as important but the device is not supposed to be working by stiction.

45. A further point arose on features 1K and 1L. The claim here provides that an increase in force is then momentarily required to push the plunger deeper into the body. By using the word "then" here the claim is referring to the correct sequence of events. In features 1I and 1J the plunger is at the stop position, engaging with the rear of the syringe and pushing it forwards. Then at features 1K and 1L, an increase in force is needed to cause the protuberances to be squeezed inside the syringe, the plunger moves deeper into the syringe body and so pushes the piston relative to the syringe, moving the piston forwards to expel the drug.

46. There is a debate about what an "increase in force" meant. The defendants submitted that this made sense in the context of a manual device (such as depicted in the figures) whereby the user can momentarily apply an increase in force in a discontinuous way to get the plunger to move deeper inside. I agree the feature makes sense in that way but I do not accept that means it would necessarily exclude an arrangement in which the driving force would be applied by a firing spring such as one would find with auto-injectors. The reader would understand the patent was contemplating that the device could be an auto-injector. The argument really arises in the context of infringement and I will address it further there.

47. Claim 3 is as follows

Claim 3

*A mechanism as claimed in Claim 1, wherein the protuberances (84) are disposed approximately one quarter of the way along the length of the plunger (82) from the piston end.*

48. There was an issue about how the length of the plunger is defined and how to decide where the protuberances are along that length. It is convenient to address those in the context of validity.

*Infringement*

49. The Humira Pen is described in various patents and patent applications filed by the defendants. Although much of the detail does not matter, figure 16b of PCT application WO 2008/005315 ("Julian") is not a bad representation of the product:

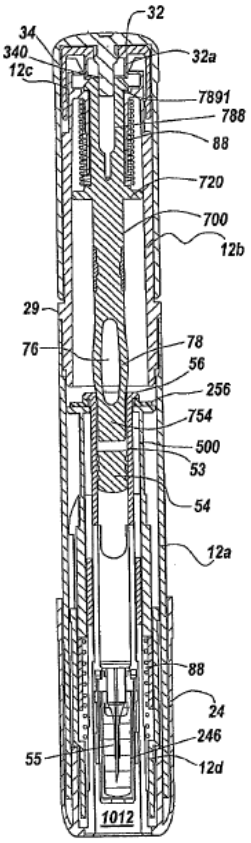



*Fig. 16b*

50. The top end of the device is a firing mechanism. There is a cap which has to be removed and then, when the device is in position, the user presses on button 32. This pushes down on barbs 7891 and slides them inwards. The barbs are on the end of the plunger. Once the barbs slide inwards sufficiently they move clear of the shelf and the plunger is now free to move downwards under the action of coiled firing spring 88 (at the top). This uncoils and drives the plunger downward. The plunger has an expanded region 76 and projecting elbows 78.

51. According to the text of Julian, the elbows rest against the end of the syringe 56, preventing the plunger from travelling within the syringe barrel. Julian states that "*in this manner all the biasing force from the first coil spring 88 is applied to move the syringe forward*" towards the end of the device. This pushes the needle outwards and into the body of the patient. Once the syringe can go no further forward Julian explains that the force of the firing spring causes the elbows to compress inwardly and slide into the interior of the syringe, the plunger can then apply pressure to the bung or piston 54 to cause ejection of the drug.

52. Mr Rolfe is also named as an inventor on the Julian patent. His evidence was that Julian accurately states how he intended and understood the device to work.

53. Mr Liversidge contends that described this way, the Humira Pen satisfies claim 1. There are protuberances (elbows 78) and a through slot (the space marked as 76). There was a point on whether the elbows were protuberances within the claim. They plainly are in my judgment. The fact that they gently protrude from the side of the plunger and do not form a steep angle is neither here nor there. There are subsidiary points on infringement but I will deal with that separately. Subject to the subsidiary points, I agree that the device described in Julian would satisfy claim 1.

54. However the defendants contend that despite Julian (and other patents to the same effect such as Bicknell) and despite the opinion of the inventor of the device Mr Rolfe, the Humira Pen does not in fact operate as described so far and does not work in the manner claimed. Instead it works by stiction. The point of Mr Murphy's experiments was to investigate whether, as the claimant contends, the elbows of the plunger were engaging with the rear end of the syringe and pushing it forwards or whether, as the defendants contend, the forward end of the plunger was striking the piston and thereby pushing the syringe forwards, relying on the stiction between the piston and the syringe.

55. Mr Liversidge criticises the defendants' experiments on various important grounds and dealing with those criticisms is an important matter I need to address. There are also points of detail about what the experiments show when scrutinised carefully and I will deal with those issues below as well. However before doing any of this I should explain what the experiments show when taken at face value. The experiments were conducted on nine randomly selected Humira Pens which each had a window cut in the external wall at the relevant point. Three unmodified syringes were also used for comparison. All pens have a window but the window in the modified pens has been cut to be larger so as to see how the plunger engages with the syringe.

56. In each test an unused pen is placed in a pen holding nest made to support the pen during the test. The nest has a metal plate with a hole in the middle. The plate rests on legs about 4 inches long. A plastic cylinder is above the hole and is fixed to the plate by a flange. The inside diameter of the cylinder is large enough for a pen to sit inside. A rubber pad is placed at the bottom of the cylinder and sits over the hole in the metal plate. A small plastic bottle is placed below the hole. To perform a test the caps at either end of the pen are removed as would happen in practice and the pen is placed inside the cylinder, with the needle end pointing downwards. A high speed camera is set up to film what can be seen through the window in the pen. In practice the firing of the pen happens very quickly indeed when the button is pressed, hence the high speed camera.

57. To trigger the device a force tester is used to drive a plate which acts on the plum coloured firing button on the top of the pen. Before firing, the button sits about 2.6mm above a lip on the gray barrel of the pen. The force tester's plate comes downwards to very gently touch the button. At that point it exerts minimal force. From then on the force tester plate moves downwards. The point of the exercise is to simulate a person pushing the button.

58. The button moves down far enough to trigger the device. Once triggered the plunger starts moving downwards as the firing spring uncoils. What can be seen on the high speed video is as follows. At the start the front end of the plunger is inside the barrel of the syringe. It is about 5mm above the piston. The plunger is accelerated by the

drive spring until it is travelling at about 3 m/s. When the plunger starts moving there is no movement of the syringe or syringe carrier. As the plunger moves downwards relative to the syringe the elbows are collapsed into the body of the syringe. The end of the plunger hits the piston. At this stage the syringe has not moved. Now, as the plunger moves down, the syringe and syringe carrier move down with it. So the plunger and syringe now move together. Thus it is not until the plunger hits the piston that the syringe/carrier assembly begins to move downwards. It is clear that at this stage, moving downwards, the piston is not moving relative to the syringe. The action of the plunger on the piston is pushing the syringe downwards. Stiction is being relied on.

59. The period between the plunger starting to move and the end of the plunger hitting the piston is very small - 0.0015s. At this point the elbows are compressed inside the syringe.

60. Mr Murphy's view was that the experiments showed that downward movement of the syringe and syringe carrier in the Humira Pen comes about due to the force applied directly to the piston by the plunger. If that is accepted then the experiments prove that the protuberances do not deliver the axial pressure to the rear of the syringe (implicit in feature 1J) and do not define the "stop position" called for by feature 1I. On the face of the experiments and based on Mr Murphy's opinion, there is no infringement.

61. A brief experiment in reply was conducted by Mr Liversidge. In this test the pen is taken apart and the firing spring taken out. The plunger is pushed down by hand. When performed that way the elbows engage with the syringe just as described in Julian.

62. It seems to me that the correct approach to resolving the issue of infringement is as follows. The legal burden of proof to prove infringement rests and remains with the patentee, Mr Liversidge. However I find that he has provided prima facie evidence that the Humira Pen does indeed infringe. This consists in part of the defendants' own patent specifications. Julian is the paradigm example and an important point on Julian is that it is a description of the pen after it had been designed, built and tested. In addition I have the evidence of the inventor of the device, Mr Rolfe, about how he designed the pen to work.

63. Without evidence to rebut it, there is ample material here on which to find for Mr Liversidge. Thus the evidential onus has shifted to the defendants to rebut that inference of infringement. Although in general defendants do not bear the burden to prove non-infringement, in the circumstances of this case, these defendants bear an evidential onus to prove they do not infringe. In my judgment it is a heavy onus. Mr Murphy accepted it would be remarkable if a device built to work in a particular way and described as working that way after it had been tested, turned out to work in a different way. Nevertheless he maintained his opinion that it did indeed operate as shown in the experiments. The key to this issue is the weight I can put on Mr Murphy's experiments. I will address that next but before doing so I should deal with Mr Liversidge's experiment in reply. It was not clear to me whether Mr Liversidge actually relied on the test to prove how the device worked in practice or whether the test was simply illustrative of how it could work. In any case I was not persuaded that that test is of any real assistance. The device alleged to infringe is the device as a

whole, driven by the firing spring. It was clear that how a device of this kind behaves will depend on factors like the magnitude and rate of application of the axial force. The fact that parts of the device, isolated from other parts, can be shown to work in the appropriate manner does not help. I will place little weight on Mr Liversidge's reply experiment.

64. Mr Liversidge takes two points on Mr Murphy's experiments. First there are criticisms of the experimental set up and second there are points arising from a close observation of the experiments and the pen device itself.

*Criticisms of the experimental set up*

65. There was a point about the selection of pens to be used in the test but this was explained in the Notice and nothing came of it. The selection had been fair.

66. The major point taken against the experiments was that they did not represent a fair test of the operation of the device in practice for a number of reasons which can be taken separately but must also be taken together. First, the cut away in the barrel will alter the behaviour of the pen. Second, the way the pen is held in the nest differs from the way it is held in practice and will alter its behaviour. Third, the way the force is applied to the button in the experiments will tend to crush the device and alter its behaviour.

67. There was also a point that the video meant one could not see what else happened elsewhere but I did not regard this a major point. I was not satisfied that there was anything material which could not be seen.

68. As a matter of principle the cut away will weaken the outer sleeve of the pen to some degree and again, as a matter of principle, that is capable of influencing the mechanical behaviour of the mechanism as a whole. However I was not persuaded that this cut away had any material effect. Some lateral movement is visible in the video footage but it is very small and Mr Murphy did not believe it would influence the fundamental sequencing of the system on activation. The experiments also included control experiments conducted without a cutaway. In the controls it is not possible to see as much of the action of the plunger (that is why the cut away is needed) but one can see that the modified and unmodified pens work in the same way.

69. As for holding the pen, it is true that the nest does not hold the pen in the same way as a patient would but again I was not persuaded this was a material point. There was an issue about whether the rubber pad simulates the resilience of human skin but that is not relevant in my judgment. The behaviour of the device which is relevant takes place before the needle has to start pushing into the skin (or rubber) and so even if the properties of the rubber pad were very different, it would not matter.

70. The point about a crushing force being applied to the button was as follows. Once it starts advancing downwards to press the button the force tester is relentless. If it met resistance, it would push with a force much stronger than a human finger. The furthest distance the plum coloured button can travel relative to the pen is about 2.6mm whereas the force tester moves down a total distance of 3mm. Therefore, it is argued, once the force tester has pushed the button down 2.6mm and onto the ledge on the pen, the force tester will keep on pushing downwards inexorably a further

0.4mm or so and crush the device. This crushing force will squeeze the mechanism as a whole in an unintended manner and may alter its behaviour. This is all the more significant given that the pen is not held laterally in a normal way and given that the strength of the barrel has been weakened by the cut away.

71. I reject this point. First, the force tester is moving very slowly relative to the speed of the triggering events. I am not satisfied that any crushing effect could even have started by the time the plunger has been triggered and has engaged with the piston. If the crushing happens after the events seen in the high speed videos of the experiments then even if it takes place it is irrelevant. Second and in any event the pen is resting on a rubber pad. There is quite sufficient play in the rubber to allow the pen to move downwards as a whole under the action of the force tester once the plum button has reached the end of its travel. Thus even if the crushing would otherwise start at or before the triggering of the plunger, all that will happen is that the pen will be pushed slightly into the rubber pad. That drastically reduces any crushing tendency. All the irresistible force of the force tester will do is push the pen, uncrushed, into the rubber pad a little bit.

72. It was submitted that Mr Rolfe's opinion was that the strong downward force would have an effect before the device fired. I did not find his evidence on that to be very clear but in any event there was nothing in it which persuaded me that any effect before firing was likely to be significant.

73. Mr Murphy's opinion was that the experiments carried out were representative of the actual operation of the Humira Pen in real life. To the contrary Mr Rolfe's view was that without seeing additional information or a different technique, he could not say that the videos accurately demonstrated how the Humira Pen operates. Neither expert was really shaken in cross-examination. Mr Murphy maintained that the experiments were robust and consistent with what happens in practice. Mr Rolfe maintained that the points I have mentioned above (and some other matters which were lesser points) must be the explanation for why the experiment showed the device working in a different manner from the way he designed it.

74. A point Mr Alexander emphasised was there is nothing inherently surprising as a matter of physics or engineering about the mode of operation of the device which the defendants contend for. It may not be the way the designers of the Humira Pen intended but the use of stiction is a standard phenomenon in these injector devices generally.

75. I prefer the opinion of Mr Murphy. The criticisms of the experiments are speculative and minor. In my judgment the experiments are a fair demonstration of the manner in which the Humira Pen operates in practice.

76. However although this conclusion means that Julian and the other patents do not in fact describe how the device works in practice and also means that the device in practice does not work as Mr Rolfe designed and intended it to, that is not sufficient to dispose of the issue of infringement. Mr Liversidge had an alternative case on infringement based on a close scrutiny of the experiments. It emerged in the reply evidence for the first time and I will address that now.

*A close observation of the experiments and the pen device itself*

77. It is clear that the relative geometry of the various parts means that the protuberances on the plunger are more or less entirely within the syringe barrel by the time the end of the plunger hits the piston. If the crests of the protuberances are outside the syringe when the plunger hits the piston, it is only by a very small amount. However a point on this arose in Mr Rolfe's second report. Mr Rolfe used an aluminium plug with a diameter of 6.35mm to show that bore of the syringe in the pen is not parallel. That is because this plug can only be pushed inside the barrel to a depth of about 3mm. In effect the open end of the syringe is flared to a small degree. Thus Mr Rolfe reasoned the protuberances must be performing what he called "the protuberances function" for at least 3mm of travel into the bore. In other words, because the open end is flared, the protuberances are pushing on that angled surface of the inside of the syringe.

78. I accept Mr Rolfe's evidence that there is some flaring of the open ends of the syringes. However the degree of flaring is plainly tiny. I also accept that there will be a force acting between the elbows and the inside rear corner between the barrel of the syringe and the flange. The question is what effect all this has.

79. At first sight looking at the videos of the experiments, when the plunger starts moving there is no movement of the syringe. However, after Mr Rolfe had appreciated the flaring point he noticed that when one looks closely at some of the videos, it can be seen that as the protuberances enter the very top of the syringe body there is a very small amount of movement of the syringe or syringe carrier before the plunger hits the piston. This confirmed Mr Rolfe's view that the protuberances are acting as intended to push the syringe body forward. He could not quantify the contribution made by the protuberances in this respect but he did not accept it was *de minimis* or trivial.

80. Mr Murphy accepted that there was some movement of the syringe flange visible in the videos Mr Rolfe referred to. It was in the region of 0.1 to 0.2 mm and Mr Murphy thought it was what one might expect in the compliance of the soft pad that is on top of the syringe carrier. Mr Murphy accepted in cross-examination that the elbows will have a tendency to move the syringe forward but he was not asked about the extent of that contribution. In re-examination Mr Murphy explained that the change of diameter in the flare is in the region of hundredths of millimetres of a difference and he would question whether the action of the protuberances on the bore of the syringe in the case of a flared device, was noticeably any different to the case if the bore was not flared. He stood by his opinion that the most significant element causing the forward travel of the syringe is the plunger and any influence of the elbows is entirely negligible.

81. I prefer the opinions of Mr Murphy on this issue. Given the dimensions, it is entirely implausible that the flaring makes any difference at all and it is also implausible that there is any material contribution from the elbows acting on the inside rear corner of the syringe. The movement of the syringe (or perhaps just the pad on top of the syringe) is minute. It may only consist of movement of the syringe relative to the syringe housing. The movement is not visible in other videos. Mr Rolfe's view was that was because they were hard to analyse. I do not accept that. Once it has been pointed out, the motion can be seen in the videos in which it is present. It is not present in the other videos. From the videos overall, and including the ones in which this initial motion of the syringe can be seen, it is clear that the real cause of the motion of the syringe is the plunger pushing the piston. Mr Rolfe was not able to

quantify the effect of the protuberances acting in the rear of the syringe. In my judgment it will be negligible.

*Infringement overall*

82. Looking at the issue of infringement overall, the defendants have discharged the heavy onus on them to prove that the Humira Pen does not infringe. I find as a fact that the way the Pen works is by relying on stiction between the piston and the syringe. To move the syringe the plunger has to push the piston. A difficult question of claim construction might arise in a case in which the action of the protuberances on the rear part of the syringe made a non-negligible contribution to the motion of the syringe but I reject that case on the facts. At most the contribution of the protuberances engaging with the syringe is trivial. There is no infringement. Features 1I and 1J of claim 1 are not satisfied.

*Infringement - subsidiary points*

83. Since I have held that the Humira Pen does not satisfy the fundamental parts of claim 1, the subsidiary issues on infringement do not matter but I will state my conclusions on them briefly:

    i) Feature 1F is satisfied. In the Humira Pen, the outer sleeve does not slide rearwardly relative to a patient's body, it is the syringe which moves forward. However feature 1F is talking about relative movement between the sleeve and the syringe. Relative to the syringe, the sleeve of the Humira Pen slides rearwardly.

    ii) Feature 1G is satisfied and so is claim 3. The crests of the elbows are 27% of the way along the length of the plunger, when that length is considered to be the length between the flange on which the driving spring acts and the piston end. I address the issue of construction of this feature below.

    iii) The aspect of feature 1K about a momentary increase in force is tricky to deal with in the context of the Humira Pen. The actuation is driven by a spring which uncoils and produces a gradually declining force. The idea of a need of an increase in force being momentarily required makes more sense when one is thinking about a manually operated device. However taking the granted patent at face value, I think the reader would understand that feature 1K should be able to be satisfied by an auto-injector driven by a spring. As a matter of common sense, with elbows on the plunger more force will be needed to push the plunger and squeeze the elbows at the same time than will be needed just to move the plunger inside the barrel of the syringe. That extra force must be what the claim is referring to in the context of auto-injectors even though one cannot require the drive spring to deliver an increase in force at any given moment. I think 1K is satisfied.

84. I do not need to consider the question arising in relation to infringement under s69 of the 1977 Act.

*Added matter (s76 of the 1977 Act, Art 123(2) EPC)*

85. The law on added matter is well settled. The correct approach was explained in ***European Central Bank v DSS*** [2008] EWCA Civ 192 (Jacob and Lloyd LJJ and Sir John Chadwick). In paragraph 12 of the judgment of the court Jacob LJ approved the summary of the law by Kitchin J (as he then was) in that case. I will not set it out in this judgment. I also bear in mind the description of intermediate generalisation given by the Court of Appeal in ***Vector v Glatt*** [2008] RPC 10, referring back to Pumfrey J (as he then was) in ***Palmaz's European Patents*** [1999] RPC 47. The parties also referred me to my own judgment in ***Smith & Nephew v Convatec*** [2012] EWHC 1602 (Pat) at paragraph 88 in which set out how I understood the reference by Pumfrey J to features not being disclosed as having inventive significance. I also remind myself that it is important to distinguish between the disclosure of subject matter and the scope of the claim. This point arose in ***AC Edwards v Acme Signs*** [1992] RPC 131 and was recently reaffirmed in ***Gedeon Richter v Bayer Pharma*** [2012] EWCA Civ 235 (see paragraph 17).

86. There is no question that in this case very extensive amendments have been made between the application as filed and the patent as granted. However just because the amendments are substantial, it does not mean that matter has been added. Each case must be decided on its own facts.

*The issue*

87. The patent arises from a divisional application filed on 24th March 2009 based on the earlier PCT application WO 2004/000397 which itself was filed on 23rd June 2003. It was common ground that the question of added matter needs to be judged as between the original parent application and the patent as granted.

88. The divisional application was based on the text and figures relating to a single embodiment disclosed in the PCT application. In the PCT it was called the sixth embodiment and was depicted in figures 7A to 7J. In addition to the text relating to the sixth embodiment, further text was added at the start of the divisional application to describe the sequencing problem and review the prior art.

89. The defendants' case is as follows. The original application was for an invention that relates to a safety arrangement for a medical needle or injector. The invention in the application was intended to solve the problem of needle stick injury by providing automatic (also called passive) protection. It was not intended to solve the sequencing problem, which is not mentioned anywhere, and it did not disclose a solution to that problem. The application did not disclose the features claimed by the now granted patent separately from the safety arrangement mechanism. The patent discloses an entirely new problem and solution not disclosed in the application. The application did not identify any aspect of the protuberances as being inventive or having technical significance to the overall composition of the injector or its mechanism either in the context of the assembly in figure 7 itself or the wider context of the application as a whole. By claiming some of the features of figure 7 when they were only disclosed in the context of figure 7 and were not disclosed as having inventive significance and omitting the features above, claim 1 of the patent amounts to an intermediate generalisation.

90. The defendants argue that the following features that were a requirement of the sixth embodiment are now missing from claim 1:

i) The plunger has an X-shaped cross-section and each arm of the X-shaped cross-section is provided with a protuberance

ii) Each protuberance is disposed approximately one quarter of the way along the length of the plunger from the piston end

iii) The syringe body is fitted with a needle during the course of manufacture

iv) The sleeve has an annular shoulder part way along its length which engages with that part of the tubular support housing the syringe that has a thickened wall

v) A helical compression spring acting between an internal rib of the tubular support that houses the syringe and an internal flange of a tubular blocking member.

91. Points (iv) and (v) are the manifestation in claim 1 of the problem caused by separating the protuberances from the context of a disclosure concerned with a safety arrangement. The other points are free standing added matter objections.

92. Mr Liversidge denies the charge of added matter. His case is that the invention of the patent is disclosed in the application. The characterising portion of claim 1 comes from p16 ln 6-15 of the PCT application (which now forms paragraph [0020] of the patent). An important part of that teaching is the statement that the plunger differs from the plunger of a conventional syringe in that the outer edge of each arm of the X-shaped cross-section is provided with protuberances. He contends that this shows that the feature has inventive significance in its own right.

93. He argues that the passage at p18 ln3-9 (which corresponds to paragraph [0026] as granted) directly and unambiguously teaches the skilled reader that the protuberances are a solution to the sequencing problem. The sequencing problem was part of the common general knowledge and so the reader would see in the PCT application that the protuberances are indeed a solution to that problem. The other features of the sixth embodiment which are disclosed would be understood as having nothing to do with the protuberances feature and nothing to do with the sequencing problem. Thus there is no added matter.

94. In summary the debate between the parties relates to four points: first the safety arrangement, second the X-shaped cross-section, third the location of the protuberances along the plunger, and fourth the needle being fitted in the course of manufacture.

95. For the reason I gave in ***Smith & Nephew v Convatec***, I will not focus on whether features are stated to have "inventive significance" as such.

*The disclosure of the application as filed*

96. There is no doubt that the focus of the application is on a safety arrangement for a syringe. This can be seen from the first sentence of the document ("This invention relates to a safety arrangement for a medical needle ...") but is clear from the document as a whole. The problems discussed relate to safety and needle-stick injury.

The need identified is for a protective device which offers a high protection against needle-stick injury. It is highly preferred that the protective device operates fully automatically. The consistory clauses (p2 ln 29 et seq) describe a safety arrangement based on a blocking member and control means. That is the invention being described. Various options are described but they are all variants on the same theme. I will characterise it as the use of a blocking member although it could be described differently. Eleven embodiments are described along with some variants. The figures range from figures 1 to 13. They all have safety arrangements based on blocking members. The blocking member is item 23 in the first, second, third, fourth and fifth embodiments, item 97 in the sixth, seventh and eighth embodiments and item 131 of the ninth embodiment. The blocking member is also item 97 in the embodiments of figure 12 and figure 13. (Figure 13 is called the eleventh embodiment at p8 ln10 but the tenth embodiment at p25 ln2).

97. The disclosure of a plunger with protuberances in the sixth embodiment is a disclosure the skilled reader would see firmly in the context of the safety arrangement invention being described in the document as a whole. The protuberances in that embodiment clearly operate in the manner now claimed and address sequencing (p18 ln3-9 of the application) but they are operating in the context of an injector as a whole which has a safety arrangement to avoid needle stick injury. The skilled reader would not see in the sixth embodiment a disclosure of a device purely to address the sequencing problem. The disclosure is of a device which has the safety arrangement with which the application overall is concerned and which also has the protuberances. At most it is a device which addresses both safety (in a particular way) and sequencing.

98. I recognise that the application does expressly draw attention to the fact that the presence of protuberances causes the plunger to differ from the plunger of a conventional syringe. However this does not help. It is an aspect of the sixth embodiment which makes it differ from known devices but that is a long way from saying it is something in and of itself to be used in injectors generally. There is nothing here to suggest to the reader that the disclosure has now moved out of the context of devices with safety arrangements. I do not think a skilled reader would understand this as a disclosure that the plunger in question was to be used separately from the safety arrangement. That invention, in other words the idea that the protuberances could be employed in a syringe which did not have the safety arrangement described, simply does not exist in the application. It is not expressly disclosed and it is not implicit.

99. On the second question (X-shaped plunger) the matter is more balanced. It is not obvious reading the application why it might matter that the plunger is X-shaped. However it seems to me that, as a matter of disclosure, the only thing described is an X-shaped plunger. The protuberances are on the arms of an X-shaped plunger. The key disclosure (p16 ln6) is that:

> "The plunger 82 has an X-shaped cross-section and differs from the plunger of a conventional syringe in that the outer edge of each arm of the X-shaped cross-section is provided with a protuberance 84, disposed approximately one quarter of the way along the length of the plunger, from the piston end."

100. This is a teaching that what makes the plunger differ from that conventional X-shaped cross-section is the presence of the protuberances. What the skilled person has to do to make the plunger disclosed is start from a conventional X-shaped plunger and add protuberances. It is not a teaching that the X-shape is optional.

101. If claims had been drafted in the application which related to the protuberances then one might or might not have seen claims which showed that the X-shape was not important. However there is nothing in the document by way of generalisation apart from the specific disclosure of the sixth embodiment.

102. On the third point (location of protuberances along the plunger), the application simply teaches that the protuberances are "disposed approximately one quarter of the way along the length of the plunger, from the piston end" (p16 ln8-9).

103. I do not accept the fourth point (needle fitted in the course of manufacture). Although the sixth embodiment does indeed state that it relates to an arrangement in which the syringe has a body with a needle fitted in the course of manufacture, read in the context of the application as a whole and the other embodiments, a needle fitted in the course of manufacture is not an essential element of what is disclosed in the application. In this way it is unlike the issue of the general idea of a safety arrangement with a blocking member (which is essential in the document as a whole) and unlike the X-shaped plunger (which is an essential part of the disclosure of the protuberances). I need not consider this point any further.

*The disclosure of the patent*

104. The patent is not focussed on the safety arrangement at all. The patent contains a clear disclosure of the protuberances as a solution to the sequencing problem in general terms. Consistent with this the patent refers to auto-injector devices, which is the context in which sequencing is really an issue. The invention disclosed in the patent does not need to have the safety arrangement depicted in the figures. That is clear from paragraphs [0001] to [0016] and claims 1 to 4.

105. As for the X-shaped cross-section, the disclosure of the patent could not be clearer. Paragraph [0016] states that the plunger "may" have an X-shaped cross-section that defines a plurality of arms. In other words it is optional. That paragraph is not in the application as filed.

106. On the location of the protuberances along the plunger, claim 1 states that the protuberances are "disposed partway along the length thereof" in feature 1G. This wording is not merely a broader claim as compared to the application (cf ***A C Edwards v Acme***) it is a clear disclosure that the protuberances can be anywhere along the plunger as long as it can be described as "partway" along.

*The disclosures compared*

107. Taking the safety arrangement point first, in my judgment it is plain that there is added matter. The teaching of the patent relegates the safety arrangement to an optional extra. The patent cannot be said to be merely an example of a broader claim but not a broader disclosure. The patent amounts to a clear, focussed teaching about the protuberances as a general solution to sequencing. It is nothing to do with a

needle stick safety arrangement. A skilled person reading the patent and putting it into practice would build a device with protuberances. Whether they went on to seek to include the safety arrangement which is also described would be a matter of choice. The skilled person would certainly not think they were required to include the safety arrangement described. On the other hand a skilled person reading the application would never construct a device which did not have one of the safety arrangements described in it.

108. The fact that the skilled person knows the sequencing problem from their common general knowledge does not justify creating an entirely new introductory section in the patent which describes that problem. It is not an answer to added matter to say that the matter which was put in was all purely common general knowledge. Furthermore this is not a case in which merely inessential features have been removed. There was nothing inessential about the safety arrangement in the parent application.

109. The extent and significance of the changes between the application and the patent can be seen by considering the safety arrangement in the context of auto-injector devices. The application related to a fully automatic safety arrangement. The application was not concerned with auto-injectors but the patent, with its focus on the sequencing problem, is (at least in part). However on the evidence before me, there is no way of using the fully automatic safety arrangement disclosed in the application in an auto-injector device. The two aspects conflict. This is dealt with in the insufficiency section below. The defendants did not submit this conflict gave rise to a free standing objection and I agree. However it does emphasise the difference between what was disclosed in the application and what is now disclosed and claimed. Another example is the meaning of feature 1K (increase in force required). This makes sense in the context of the manually driven embodiment disclosed in the application but does not sit comfortably in the context of an auto-injector.

110. This is a case in which the warning about hindsight given by Kitchin J in ***European Central Bank v DSS*** and approved by the Court of Appeal is relevant. It is too easy to start from the granted patent, in which the protuberances are described in the context of a discussion of the sequencing problem (which discussion is not in the application) and in the context of a discussion of prior art related to that problem (which discussion is not in the application). When one reads the patent, even though the safety arrangement with the blocking member 97 is described, it is not an essential element of the disclosure. Apart from anything else it is not claimed at all. However when the parent application is read without hindsight and without the text added at the start of the patent about the sequencing problem, the disclosure is very different. The document from beginning to end (including the claims) is about a safety arrangement.

111. I will not speculate whether it would have been obvious to a skilled reader of the application that the protuberances could be used without the safety arrangement because that is not the test for added matter. It would be speculation but one cannot help but wonder if the idea of using protuberances separately from the safety arrangement in the application only occurred to the patentee in this case after seeing the Humira Pen.

112. Taking the X-shaped cross-section, again I find there is added matter. It is disclosed in the application as part and parcel of the protuberances. It is an intrinsic part of the

only disclosure in the document of the protuberances. However the patent simply states that the plunger *may* have an X-shaped cross-section. That is new information and added matter.

113. Regarding the location of the protuberances along the plunger, that is also clear added matter. The problem is that the application discloses that the protuberances have to be approximately a quarter of the way along the length of the plunger while the patent discloses that they can be partway along the plunger. It is true that the evidence before me was that the skilled reader would not regard the precise location as important but that does not mean there is no added matter. A reader of the application would be directed to make a device with the protuberances a quarter of the way along the plunger. He would not have in mind any other location for the protuberances along the plunger. Whereas a reader of the patent would think of putting them anywhere partway along the plunger. That could be half way along. However the issue about location only relates to claim 1 and not claim 3. Claim 3 limits the claim to the disclosure of the application.

114. In summary I accept points (i), (ii), (iv) and (v) about claim 1. I reject point (iii).

115. This case is a paradigm example of the kind of unwarranted advantage to an applicant and damage to legal security of third parties which the EPO Enlarged Board referred to in case G-1/93. A reader of the parent application in this case would see it was concerned with a safety arrangement from beginning to end. There was no disclosure of any other kind of injector and no claims to anything which did not use the safety arrangement described. Third parties were entitled to file this one away as an application about a particular needle stick safety arrangement and not worry about it any further save in that context. To find many years later that the application has spawned a patent which is not based on those safety arrangements would be an unwelcome surprise.

116. One might ask how the patent office could have allowed such a wholesale extension of subject matter to slip by. The fact the patent office allowed the amendments does not justify them but in this case there may be a partial explanation. The divisional application itself contained much more of a description of the automatic safety arrangement than the granted patent (see e.g. paragraphs [0013] to [0016] of the divisional application EP 2 067 496 A). In addition to the claims to the device with protuberances, in the divisional application there were also dependent claims to the device with protuberances and the safety arrangement. During prosecution of the divisional application the general disclosure and claims relating to the safety arrangement were deleted, leaving a patent focussed entirely on the sequencing problem and the protuberances. Thus the step from the parent PCT application to the divisional does not look as large as the step from the parent PCT application to the granted patent. It may be that this explains why the examiner did not pick up on the point.

*Novelty*

117. The claims I have to consider are claims 1 and 3. The defendants say they are both invalid as lacking novelty over two items of prior art: Post and Sarnoff.

*Post*

118. Post is a US Patent published in 1973. The object of the invention is to provide a hypodermic syringe in which the instant at which the pressing out of the liquid out of the liquid container begins is determined unambiguously by the construction of the syringe. In other words it is concerned with sequencing. The device is driven by a compression spring. The way in which sequencing is achieved is to have "blocking elements" at a defined position. The blocking elements engage with the end of the liquid container to allow it to be pushed forwards. Once the needle is projected from the sleeve, a bevel on the housing (item 50 in the figures below) operates to push the blocking element(s) inwards. This allows the plunger (called a pressure member) to push the piston inside the barrel of the liquid container and expel the drug.

119. Figures 1 and 2 of Post are:

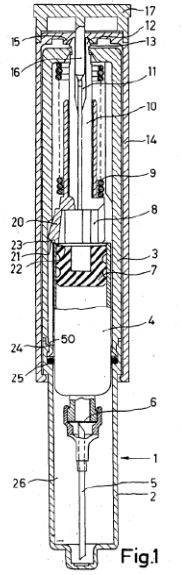


Fig.1

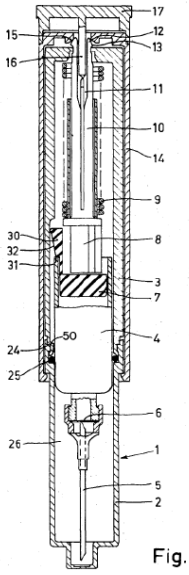


Fig. 2

120. It is worth noting that in figure 1 the blocking element (lug 20) is mounted on the plunger (8) whereas in figure 2 the blocking element (lug 30) is mounted on the piston. Post makes it clear that either arrangement can be used. In both arrangements there is a space in the plunger for the lug to move into when it is moved radially inward.

121. The blocking elements may have a variety of constructions. Mr Abrahams counted eight suggestions in Post for blocking elements. They were (i) fig 1, (ii) fig 1 but with the lugs connected to the piston, (iii) fig 2, (iv) fig 2 but with the lugs connected to the plunger, (v) plunger, piston and lugs a single assembly, (vi) the arrangement of fig 3 which uses an annular segment, (vii) an arrangement with spring driven pawls in a groove in the piston, (viii) spring driven pawls in a groove in the plunger.

122. The features of claim 1 which Mr Liversidge contends are not disclosed in Post are features 1G and 1H. It is clear (and I find) that the blocking elements which are lugs or pawls are protuberances within the meaning of Mr Liversidge's patent. The issue for feature 1G is concerned with their location. The issue for feature 1H is about "through-slot".

123. Taking feature 1G first, can it be said that in Post the protuberance is "*disposed partway along the length*" of the plunger? The issue is whether feature 1G excludes a

protuberance near the end of the plunger. There is nothing in Mr Liversidge's patent to indicate to the skilled reader that it should. The diagram in Mr Liversidge's patent shows protuberances some way from the piston end and shows the plunger some way inside the syringe at the start but all feature 1G requires is for the protuberance to be part way along the length. That is unspecific. I find that the protuberance in figure 1 of Post is disposed partway along the length of the plunger.

124. Considering feature 1H, it is fair to say that the expression "through-slot" is not very apt to describe figure 1 of Post. However that is in part because the term "through-slot" makes more sense when one is thinking about a plunger formed with arms in the X-shaped cross-section disclosed in Mr Liversidge's patent. Nevertheless the claim is not limited to a plunger with X-shaped arms and the term "through-slot" does not justify reading such a limitation into it.

125. The point of the through-slot is to allow the protuberances to flex radially inward. As a "through" slot there must be a slot running all the way through from one side of the protuberance to the other. I have rejected Mr Liversidge's argument that a "through-slot" must be bounded on all sides.

126. There is a space behind the lug in figure 1 to enable its inward movement. That space runs all the way through from one side to the other. I find that in figure 1 of Post, in the region of the protuberances, the plunger has a through-slot to enable radially inward movement of the protuberances. Feature 1H is satisfied and so claim 1 lacks novelty over Post.

127. Claim 3 requires that "the protuberances are disposed approximately one quarter of the way along the length of the plunger from the piston end". This raises two questions. First, how much of the length of the pressure member 8 in Post counts as the length of the plunger from the point of view of claim 3? Second, what part of the protuberance is to be taken into account in locating it along the length of the plunger?

128. On the first question, as I read it the length of the plunger referred to in Mr Liversidge's patent is the length from the piston end to the place where the axial force acts on it. The matter is somewhat arbitrary. It does not appear to matter how long the plunger is. In Mr Liversidge's patent the plate against which the axial force pushes cannot go inside the barrel and that at least sets a minimum length for the plunger. However in Post the flange on which the force is applied looks like it could fit inside the barrel of the syringe. Nevertheless I think the only realistic interpretation of the claim is the one which makes the relevant length the distance between the piston end and the plate or flange against which the axial force pushes. Thus in fig 1 of Post the length of the plunger runs from the piston end to the flange on which the spring 9 acts. It does not include the extra length of material in item 8 which is inside spring 9. That extra length is irrelevant.

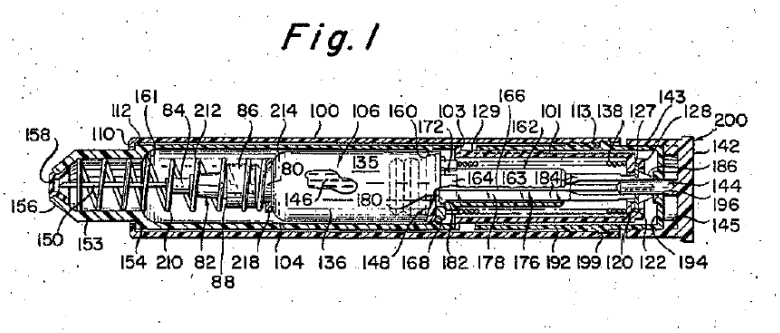
129. On the second question, one could consider the location of a protuberance to be the crest of the protuberance or to the place where it meets the plunger (the hinge). The skilled reader would understand that claim 3 is not trying to set out a careful or precise definition but a rather generalised feature. The protuberance as a whole needs to be considered.

130. On this construction I do not think figure 1 of Post satisfies claim 3. The plunger is very short. The crest is very near the piston end and the hinge is close to the other end, about ¾ of the way along the length of the plunger from the piston end.

131. Do any other disclosures in Post satisfy claim 3? In my judgment they do not. Figure 2 shows the lug mounted on the piston and although there is a teaching to put lugs on the plunger instead, I do not see clear and unmistakable directions to do that in such a way as to fall within claim 3. Figure 3 is irrelevant and the other suggestions (pawls) again do not come with clear and unmistakable directions to put them in a location which satisfies the claim. Accordingly claim 3 is novel over Post.

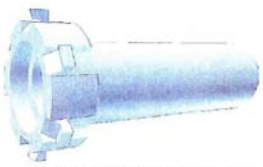
*Sarnoff*

132. Sarnoff is a hypodermic injection device with a shock absorbing spring. Figure 1 of Sarnoff is as follows:




133. The shock absorbing spring is at the front (210). The tabs (168) initially engage the end of the ampoule cylinder (136), pushing it forward. Once the needle (150) is fully introduced into the patient, the plunger (162) continues to exert force on the tabs (168) causing them to bend backwards or shear off, allowing the plunger (162) to enter the ampoule and engage the piston (148), which moves forward and expels the medicament into the patient.

134. The plunger tabs (168) are at the end of the head (164) of what Sarnoff calls the plunger (162). The figures are hard to see in Sarnoff but an image produced for this case to illustrate the plunger in Mr Rolfe's report. It is:



Graphical representation of the Sarnoff plunger-rod

135. As with Post, the issues relate to feature 1G and 1H. The tabs are protuberances within the claim. The fact they may bend or break off does not mean they are not protuberances.

136. The space behind each tab is a through-slot which allows the tab to move inwards radially for the same reasons as I have addressed in relation to Post. Feature 1H is satisfied.

137. Although the whole structure shown in the image above is called the plunger in Sarnoff, from the point of view of claim 1 of Mr Liversidge's patent the relevant length of the plunger is the length of the head – that is the wider part on the left of the diagram because that is the extent between the place on which the spring pushes the plunger and the part pushing the syringe. Although the hinge points are at the end of the plunger, the crests of the protuberances are partway along the length of the plunger. I find that feature 1H is satisfied and claim 1 is anticipated.

138. It also seems to me that claim 3 is anticipated. Again although the hinges are at the end of the plunger, the crests of the tabs are about a quarter of the way along the relevant length.

*Inventive step*

139. Although I have found that claims 1 and 3 lack novelty, I will address inventive step briefly in any event but I will do so assuming Mr Liversidge's construction of "through-slot" since on that construction the claims are novel. The right approach is the structured approach to obviousness set out in *Windsurfing International Inc v Tabur Marine* [1985] RPC 59 and adjusted in *Pozzoli v BDMO* [2007] EWCA Civ 588, [2007] FSR 37.

140. The person skilled in the art and the common general knowledge have been identified above.

141. Three general points were taken by Mr Liversidge to support the case on inventive step: first if the invention was obvious why was it not done before; second the solution provided is simple and elegant and third the defendants themselves sought to patent it.

142. On the first point, there was no evidence that industry was actively searching for a solution to the sequencing problem and not finding it until Mr Liversidge's invention came along. Engineers working on auto-injectors knew that they needed to ensure proper sequencing but they had techniques within their common general knowledge to do this, i.e. using stiction. Such engineers would be interested in alternative approaches to sequencing but that is a long way from saying there is any mileage in this first point.

143. On the second point, I agree that Mr Liversidge's protuberances are a fairly simple and elegant approach and for what it is worth I will take that into account. Its value as a point depends on the prior art.

144. On the third point, it is clear that the defendants did indeed seek patents on the Humira Pen. I do not see that any weight can be attached to this point in a case like this. To make anything of it at all one would need to start analysing the terms of the other patents and see exactly what was claimed to be inventive, over what prior art and how broadly stated the claims are.

145. In terms of inventive concept, I understood Mr Liversidge's case to be that claim 1 is a solution to the sequencing problem for an injection device with a sleeve. The patent provides protuberances on the plunger which engage with the rear end of the syringe body to project the needle forward of the sleeve without expelling medicament.

When the needle is inserted to the correct depth, the protuberances then move radially inward to enable the plunger to move deeper into the syringe body and thereby expel the medicament.

146. I should say that I do not see how feature 1G could contribute to the issue of inventive step nor how claim 3 could be independently inventive if claim 1 was obvious. There is nothing inventive in choosing a particular location for the protuberances along the plunger. It is a matter of choice for the skilled person how far forward of the protuberances the piston end of the plunger extends.

*Post*

147. The disclosure of Post has been addressed above. In terms of the inventive concept it is the same as Mr Liversidge's invention. Protuberances which protrude from the plunger (in the cases in which they do that) engage with the rear of the syringe to push it forward and then move radially inward to let the plunger push the drug out. The real difference on Mr Liversidge's construction of claim 1 is that the slot behind the protuberances is not a through-slot because it is not closed. It seems to me that given the nature of the difference between Post and claim 1, no weight can be given to Mr Liversidge's general points on inventive step. The obviousness case is one concerned with the detailed design and engineering of the devices, it is not concerned with general concepts.

148. One argument proposed by the defendants started from the disclosure of pawls. It seemed to me to be an example of the impermissible ***Technograph*** approach which is not fair to inventors. Even Mr Murphy accepted that one of the steps in the pawl argument- to use a leaf spring - would require some lateral thinking albeit that he thought that was within the ability of the skilled person. I was not convinced by the argument starting from the pawls.

149. The defendants' better argument was one starting from diagram 5(a) in Mr Murphy's report. As part of his evidence Mr Murphy proposed the following as an alternative option to figure 2 of Post, putting the blocking elements on the plunger rather than the piston:

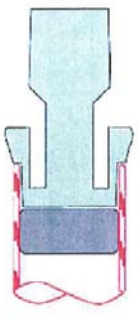


**Diagram 5(a)**

150. The diagram does not bother to deal with the engagement between the spring and plunger, it is intended to illustrate the protuberances on the plunger. The issue is about whether from this point onwards it was obvious to close off the slots in order to make bounded slots falling within Mr Liversidge's construction of claim 1.

151. Mr Rolfe accepted diagram 5(a) as an implementation of Post. Mr Abrahams emphasised that diagram 5(a) above was not a fair starting point because it was itself a step over Post. I agree that it is not fair to consider diagram 5(a) as actually disclosed by Post but in my judgment it represents an entirely obvious step. Mr Murphy clearly thought so since he regarded it as actually disclosed in Post. Diagram 5(a) above is a mere workshop modification of Post.

152. The argument here is that it would have been obvious to modify the protuberances disclosed in Post in such a way that the hinge and spacing behind them ended up as closed slots, satisfying claim 1 on Mr Liversidge's construction.

153. The defendants said it was obvious to close up the slots behind the protuberances. The reason for doing this was to improve rigidity. There was a point in evidence about a diagram 5(b) in which Mr Murphy had depicted what he regarded as an obvious step over diagram 5(a). Mr Rolfe pointed out that as drawn 5(b) was strong and un-collapsible. I agree but in my judgment that did not undermine Mr Murphy's view that it was obvious to close up the slots in 5(a) to improve rigidity. I regard diagram 5(b) is simply illustrative. Mr Murphy's view was that closing the slots was "a very natural thought".

154. Mr Rolfe did not accept this step was obvious. As I understood it an opinion he had expressed elsewhere, that change would make the injection moulding more complex, also applied to this argument. There was also a point on Mr Liversidge's behalf that if a skilled person was concerned about robustness they would start from a different embodiment of Post.

155. I bear in mind diagram 5(a) is itself a (modest) step over Post albeit one which would be a mere workshop variation arising from putting Post into practice. In my judgment claim 1 is obvious over Post. The way in which Post works is the same as the invention claimed. The only realistic difference between the claim and the prior art is nothing more than the closed up nature of the through-slots. Doing this in order to make the system more robust is a natural thing to do. I do not accept the argument that the skilled person would go for another embodiment of Post instead of taking this approach and while I accept that considerations of injection moulding are one of the things a skilled person will consider, I do not believe they would reject a change of this kind just because of the requirements of injection moulding parts. I think that even on Mr Liversidge's construction, claim 1 and claim 3 are obvious over Post.

*Sarnoff*

156. The inventive step argument over Sarnoff was that the tabs were obviously undesirable and so one would look for alternatives and arrive at an arrangement with protuberances within claim 1. I do not accept that. This argument involves abandoning in effect the whole thrust of Sarnoff's disclosure and starting again. I accept the argument put forward on behalf of Mr Liversidge here. If a skilled person did not like Sarnoff's tabs, the obvious way forward would be to use the stiction instead. It was well known at the priority date.

*Insufficiency*

157. The insufficiency argument advanced here was not a free standing attack on validity, but rather served to emphasise the problem of added subject matter.

158. On the evidence it was clear that the skilled person could not, without an inventive step, make an auto-injector device which used the fully automatic of "passive" safety arrangement disclosed in the parent PCT application. There was evidence that an auto-injector could be fitted with a safety arrangement as disclosed but the only mechanism Mr Rolfe could propose to trigger the safety system needed an extra button to be activated by the user. The problem is created by a conflict between the drive spring of an auto-injector and Mr Liversidge's particular safety arrangement. To employ a manually triggered safety system throws away the advantages of Mr Liversidge's safety invention.

159. This difficulty is or should be irrelevant to any patent granted based simply on the parent PCT application since the document makes no mention of auto-injectors. The document is describing manually functioning injectors.

160. However the granted patent, as a result of text introduced in the divisional application, is clearly aimed at using the protuberances in auto-injectors too. The Humira pen is an auto-injector. The granted patent is not insufficient because it does not claim a safety arrangement at all. But as I have addressed above, this casts light on just how significant the amendments between the application and the granted patent have been.

*Conclusion*

161. The Humira Pen does not infringe European patent EP 2 067 496. The patent is invalid on the ground of added matter. Claim 1 is anticipated by Post and Sarnoff and claim 3 is anticipated by Sarnoff. On Mr Liversidge's construction of the claims (which I have rejected), they would obvious over Post but not Sarnoff.