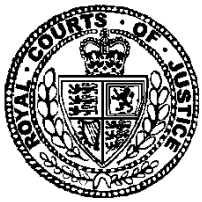


Neutral citation number [2017] EWHC 2748 (Ch)

Claim Nos. HP 2016 000050 & HP 2016 000054

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

The Rolls Building
7 Rolls Building
Fetter Lane
London EC4A 1NL
Date: Friday November 10 2017

Before: Mr Richard Meade QC sitting as a Deputy Judge of the High Court

- -

Between :

(1) Fisher & Paykel Healthcare Limited **(a company incorporated in England and Wales)** **(2) Fisher & Paykel Healthcare Limited** **(a company incorporated in New Zealand)**	**Claimants/Part 20 Defendants**

- and -

(1) ResMed Limited **(a company incorporated in Australia)** **(2) ResMed (UK) Limited** **(a company incorporated in England and Wales)**	**Defendants/ Part 20 Claimants**

- -
- -

Iain Purvis QC and Benet Brandreth (instructed by **Bird & Bird LLP**) for the Claimants/Part 20 Defendants
Piers Acland QC and Tom Alkin (instructed by **Bristows LLP**) for the Defendants/Part 20 Claimants

Hearing dates: 10, 11 and 13 October 2017

- -

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.

RICHARD MEADE QC:

INTRODUCTION

1. Obstructive sleep apnoea ("OSA") is a sleep disorder which can be treated in various ways, including "CPAP" (which stands for "continuous positive airway pressure"). CPAP treatment requires the patient to wear a CPAP mask. These matters are explained below in relation to the common general knowledge.

2. The parties are medical device companies and competitors in relation to CPAP masks.

3. These proceedings were begun by the Claimants, to whom I will refer collectively as "FPH", seeking revocation of three patents owned by the First Defendant and concerning CPAP masks, as well as declarations of non-infringement in relation to three mask designs. The Second Defendant is an exclusive licensee and I will refer to the Defendants together as "ResMed". These proceedings were triggered by ResMed having brought infringement proceedings in Germany.

4. ResMed counterclaimed for infringement in the UK.

5. Just before trial, ResMed indicated that it consented to revocation of two of the patents in suit: EP (UK) 1 841 482 and EP (UK) 2 373 368.

6. The remaining patent, which I have to deal with is EP (UK) 2 707 258 ("the 258 patent"). It has a priority date of 19 March 2008.

7. The issues are as follows:

   (1) The 258 patent is said to lack novelty and inventive step over two prior art citations, 'Geist' and 'Lovell'. They raise very similar issues.

   (2) FPH denies (but only faintly and only as a squeeze), and ResMed asserts, that the 258 patent is infringed by FPH's Simplus and Eson masks (there were three masks in issue originally but the third, the Eson 2, dropped out when ResMed gave up on the other two patents, any allegation that it infringed the 258 patent having been dropped earlier on).

8. By the time of this trial it was apparent that the real issue was validity, since although there was a squeeze FPH's primary position was a claim scope on which there would be infringement, and there was no factual dispute about infringement.

9. Accordingly, Mr Purvis QC (who appeared with Mr Brandreth) opened the case for FPH. Mr Acland QC argued the case for ResMed, with Mr Alkin.

THE EXPERTS

10. ResMed put in reports from Ms Stephanie Romiszewski, a sleep physiologist, to explain OSA and to cover which CPAP masks were in use at the date of the 258 patent. FPH did not have an equivalent expert but this did not matter because Ms Romiszewski's evidence was accepted.

11. So the real issues arose on the evidence of the CPAP mask designers. ResMed called Mr Stuart Plascott and FPH relied on the evidence of Mr John Shi-Nash.

12. Each side criticized the other's expert to some degree, but it was not disputed that each had real practical experience of CPAP design at around the priority date.

13. Mr Plascott worked for ResMed until 2015, still retains a shareholding in the company, and worked closely with the inventors of the 258 patent during his time at ResMed. Indeed the work on the 258 patent was a precursor to a design he had worked on. Understandably, FPH submits that this could cause him, and did cause him, to lack objectivity and independence.

14. I do not accept this, however, because I did not detect any such lack during his oral evidence.

15. FPH also pointed to the fact that Mr Plascott's written evidence defended positions (the inventiveness of the two abandoned patents and ResMed's construction of "shroud") which even ResMed had abandoned. I have no way of knowing what happened on the other patents (other than that ResMed gave up) and I did not think Mr Plascott's position on "shroud" was so weak as to be capable of founding a criticism of him personally; I think ResMed probably abandoned it for tactical reasons. So I do not attach weight to that either.

16. I did think Mr Plascott was on the stubborn side (but then so was Mr Shi-Nash) and I thought he overstated the difficulty of CPAP mask design, but while I take them into account these are minor matters.

17. Turning to Mr Shi-Nash, ResMed pointed out that he has numerous patents to his name, and describes himself as a "serial innovator" in his LinkedIn profile. He clearly is a person capable of innovation, but that does not mean that he exercises the capability all the time. The question for me is whether he was able to put it aside when giving his views on obviousness, and I am sure that he was. He was plainly well aware that he should put himself in the shoes of a skilled team with no inventive capability and I find that he did so.

18. Mr Shi-Nash was also criticized for the way he dealt with the cited prior art. Both citations describe the engagement between the shroud and the collar as being an interference fit, but in each case Mr Shi-Nash left this out and referred to there being a "snap-fit", which is the phrase used in the claims of the 258 patent but which does not appear in the prior art.

19. Mr Shi-Nash was adamant that he had formed his views on the prior art before he saw the 258 patent, and ResMed accepted (and so do I) that he was truthful in this. But it remains, rather unsatisfactorily, something of a mystery how it happened that he used only the expression "snap-fit". I accept in relation to both citations that it is apparent that there is a degree of snap-fit (which does not exclude there also being interference), but there was still a lack of care in the way Mr Shi-Nash dealt with this. However, it was not in any way dishonest and I do not think it should lead me to discount his evidence generally.

20. I have already said that, like Mr Plascott, I found Mr Shi-Nash on the stubborn side.

21. The upshot is that I have two well-qualified experts trying to assist the Court on matters of opinion, with each being subject only to minor criticism that did not materially undermine their reliability or objectivity. I have to decide whose views I prefer on the objective basis of what they said.

THE SKILLED TEAM

22. From the written evidence and skeletons there appeared to be some disagreement about the identity of the skilled team. The main disputes concerned whether the team would have manufacturing as well as design expertise and whether the team would need a member who could provide input about clinical aspects of OSA.

23. All of this fizzled out. There would need to be a CPAP mask designer, but no reason for distinguishing manufacturing from design remained. The team would need to understand the basics of the clinical characteristics of OSA and its treatment with CPAP. Whether they obtained this from their own experience, reading, or having someone in the team such as Ms Romiszewski is immaterial to what I have to decide.

24. References to "the skilled team" below should be understood in this light.

TECHNICAL BACKGROUND AND COMMON GENERAL KNOWLEDGE

25. The following account of the agreed common general knowledge is based on the skeleton argument of ResMed, which I have edited as necessary for brevity and clarity.

26. I have shortened it a good deal because it included quite a lot of material that, I suspect, was only relevant to the patents which were abandoned. I have also removed most references to specific marketed designs of CPAP masks, not because I disagreed but because it is not of much relevance and can be confusing.

27. There were minor areas of disagreement on the common general knowledge which I will deal with below.

Obstructive Sleep Apnoea

28. OSA describes a condition in which there are frequent pauses in breathing during sleep caused by complete (apnoea) or partial (hypopnoea) obstruction of the upper airway.

29. OSA is caused by the muscles in the soft palate, the uvula (the extension of the soft palate which hangs from the roof of the mouth), the tongue and the tonsils relaxing during sleep. Such relaxation may result in closure of the airways, causing breathing to

stop, waking the sufferer partly or completely. In people with OSA this cycle happens many times per night making it almost impossible to get any proper sleep.

Management of OSA

30. Patients can take positive action to manage the disorder in mild to moderate cases. These include weight loss, change of sleeping position and reduced alcohol intake. For more severe cases of OSA, the only really effective treatment is CPAP therapy.

CPAP therapy

31. CPAP works by forcing air into the upper airways and preventing them from closing. The equipment required for CPAP therapy has three components; an air pump which generates the air flow (referred to colloquially as a CPAP machine), a mask which is connected to a patient's face or nostrils, typically secured by some form of headgear, and a tube or hose which acts as a means of connecting the two. The air pump takes air from the atmosphere and gently pressurises it. The air then blows through the connecting tube and mask and into the upper airways. The pressure of the air keeps the airways open whilst the patient is asleep.

Types of CPAP Mask

32. Several types of masks available for CPAP therapy were available at the priority date. The most common masks were as follows:

    (1) Nasal mask – this type of mask just covers a patient's nose. Nasal masks are available in a range of different shapes and sizes to account for the differences in the shapes and size of patients' faces and other anthropometric variations. Nasal masks are advantageous for patients who breathe through their nose when asleep and for those patients with facial hair (as a better seal is easier to achieve) but less popular with patients who breathe through their mouth when asleep or who have nasal congestion.

    (2) Nasal pillows (or prongs) – these masks fit inside a patient's nostrils. They have the advantage that they do not sit over the nasal bridge region thereby avoiding nasal bridge soreness and allowing a patient to wear glasses at the same time as

wearing their mask. However, the downside is that the seal may cause nostril soreness.

(3) Full face mask – this type of mask covers both a patient's nose and mouth. It is often (but not always) the first choice for CPAP patients in the UK as pressurised air is not lost when the jaw opens during sleep and it allows the user to breathe through either mouth or nose. Full face masks are also available in a range of different shapes and sizes. However, these masks require fitting over a larger area of the face and it may therefore be more difficult to achieve the desired seal and comfort. The large size of the mask can also cause claustrophobia.

33. The following types of mask were far less common:

(1) Hybrid full face mask – this type of mask covers the nasal cavity and the mouth using nasal pillows and a mouth cushion. This type of mask can be effective for those patients suffering from claustrophobia but who open their mouths during sleep.

(2) Total full face mask – this type of full face mask sits around the forehead and the edges of the face incorporating the eyes into the mask.

(3) Oral mask – this type of mask just covers a patient's mouth. It is essentially like a gum shield with the mask sitting over the outside of the lips and the teeth resting on the shield inside the mouth. This forms a seal and allows the patient to breathe through their mouth.

34. The trial of this action concerned mainly nasal and full face masks.

Challenges of CPAP therapy

35. In order to obtain the benefit of CPAP therapy, the patient must voluntarily wear his or her CPAP mask for long periods each night while sleeping at home (i.e. without clinical supervision). The most important challenges for compliance with the therapy therefore relate to the fit and comfort of the mask. The most common were:

(1) The comfort and fit of the mask, particularly around the nasal bridge area. The nasal bridge comprises mainly bone with minimal soft tissue coverage and is

therefore more sensitive and less able to withstand high pressure and shear forces. If a mask is fitted too tightly, it can cause skin abrasion, swelling and bruising. Leaks around the nasal bridge area can also cause pressurised air to blow into the eyes causing eye irritation.

(2) Problems with the fit and comfort of the headgear. It is necessary to strike a balance between having the headgear sufficiently secure such that it does not cause the mask to leak, and not having it so securely tightened that it causes skin abrasion or soreness.

(3) Noise. All CPAP masks make a certain amount of noise, primarily from the vents in the mask permitting the escape of exhaled air and also the CPAP air pump. Leaks in the mask system also result in noise. This may cause disturbance to both the patient and their bed partner and therefore have an effect on compliance with treatment.

(4) Ease of assembly/disassembly and cleaning. Patients prefer masks and equipment (such as headgear) which have fewer components and which are easy to assemble, disassemble and clean. Ease of assembly and disassembly is particularly relevant for patients going to the bathroom during the night or for those who want a drink whilst wearing their mask. It is also particularly relevant for elderly patients or for those with poor dexterity.

(5) Cleanliness. Dead skin cells, along with grease and residual soap can cause irritation, and not cleaning the mask and headgear properly can lead to infection.

(6) Aesthetics. Patients often feel self-conscious about using CPAP masks and equipment, particularly with new partners.

(7) The ability to wear glasses and to talk to their partners whilst undergoing the treatment. Whilst patients mainly wear their masks in bed when asleep, they may want to watch television or read before bed and wear the mask in case they fall asleep.

The CPAP masks in common use at the priority date

36. There was a dispute in the evidence about which CPAP masks on the market formed part of the common general knowledge. There were many masks available, but a large number of them were not sufficiently well known to be common general knowledge. In the end this did not matter, and the only point I need to mention is that it was accepted by ResMed that it was common general knowledge, based on marketed mask designs such as the ResMed Mirage Activa, to use snap-fits to secure the cushion to frame.

The general features of CPAP masks

37. Nasal and full face CPAP masks generally have in common the following features: (1) cushion; (2) frame; (3) forehead support; (4) elbow; (5) vent; (6) anti-asphyxia valve ("**AAV**") and (7) headgear (save that nasal masks do not require an AAV).

(1) Cushion

38. The cushion is the component of the mask which sits against the patient's face and creates a seal. A challenge for a mask designer is to design a cushion which achieves a good seal while remaining comfortable and is capable of fitting a range of different face shapes and sizes.

39. The areas where it is most difficult to achieve a good seal are the cheek and nasal bridge regions. The cheek region is problematic as there is no underlying bone structure. In the nasal bridge region, there is great variation between individuals and the nose can slope sharply away from the surrounding cheek area. As indicated above, this area also has little tissue, making it prone to soreness.

40. CPAP mask cushions are commonly made from a soft, biocompatible material such as silicone. Silicone's primary benefits are its softness and stretch, bio-compatibility and capability to be moulded into both thick and very thin sections. Silicone cushions can be made by compression moulding or injection moulding.

(2) Frame

41. Together with the cushion, the frame forms the chamber into which the pressurised air is delivered. The frame provides structure so that the cushion is held in the correct

position against the patient's face. It is also the component to which the headgear and elbow are typically connected. The frame needs to be both lightweight and robust; polycarbonate was used in well-known masks. Advantages of polycarbonate include its clarity, cleaning ability (i.e. resistance to chemicals and heat), dimensional stability (which was important in the design and manufacture of vents/leak interfaces and cushion attachment), and strength.

(3) Forehead support

42. A forehead support, if used, stabilises the mask on the face, enabling a more consistent seal, and distributes the headgear forces to the relatively more robust area of the forehead away from more sensitive areas such as the nasal bridge. However, forehead supports can be uncomfortable, can restrict the patient's use of reading glasses, obscure the line of sight and increase the general physical bulk, weight and complexity of a mask.

(4) Elbow

43. The elbow connects the hose or tubing to the frame. In a CPAP mask, the elbow usually forms part of an assembly with a "swivel" that allows the hose to rotate relative to the frame while remaining airtight.

(5) Vent

44. The vent allows exhaled air to escape into the atmosphere. It is therefore a 'controlled leak', designed by a specialist to allow a known amount of air to flow through the vent at a given pressure. The vent should not block inadvertently in use and must be easy to clean. The mask designer would also seek to minimise the noise made by the vent and to direct the escaping air away from the wearer and any bedfellow as much as possible. However, there was no generally accepted approach to solving these problems; in some common general knowledge designs the vent was on the elbow, and in some it was on the frame.

(6) AAV

45. The AAV prevents the wearer of a full-face mask being asphyxiated if the CPAP pump fails or the air path is otherwise occluded whilst the patient is wearing their mask. It is an important safety feature of all full face masks but was of little relevance to the argument at trial.

(7) Headgear

46. The headgear holds the mask frame onto the patient's head. It must enable the mask cushion to maintain an effective seal when the mask is pressurised. The forces acting on the mask are largely determined by the geometry and fit of the headgear.

47. A known geometry for headgear was to have two upper and two lower straps which would each attach to the mask (one either side at the top and bottom of the mask) to create a four point attachment. These would connect to a loop of fabric which (put simply) was designed to wrap around the curvature of the rear of the skull.

48. A smaller headgear footprint makes the headgear less sweaty, reduces visible bulk and makes the headgear more comfortable to fit and wear when lying down.

Materials

49. The most common materials used for mask components (excluding headgear) were thermoplastics (e.g. polycarbonate) for the rigid components and silicone for the cushion. The process of curing (i.e. cross-linking) silicone can be used to produce a range of consistencies from very soft gel to fairly rigid rubber.

Manufacture of mask components

50. Mask components made from thermoplastics and silicone were most commonly manufactured using injection moulding. Injection moulding is a high speed, automated process which allows for high volume production of objects with complex geometries to be made to a high degree of precision. The raw material is injected into the mould as a liquid at high pressure, where it solidifies.

51. Co-injection moulding is where two different materials are injected into the same mould (simultaneously or sequentially) so as to form multi-layer structures, usually a

"core material" surrounded by a "skin material". There are limitations on the material combinations that can be used; in particular the melt viscosities and mould shrinkage values of the two materials need to be closely matched, and the two materials must be able to adhere in the process.

Connections between mask components

52. Components made of multiple materials or parts could either be formed together e.g. by co-injection moulding or over-moulding; or attached together by an assembly method depending on the geometry, materials, and permanence of connection required. The skilled addressee would have been familiar with a variety of assembly methods, covering both permanent and reversible connections. The use of a mechanical assembly (as distinct from, for example, adhesive bonding) was probably the most common method of connecting components.

Interference or friction fit

53. The concept of "interference" in engineering essentially involves two structures interfering with each other as they strive to occupy the same space. An interference or friction fit (also known as a "press fit") involves one component being forced into a complementary feature of the other component despite an interference, typically resulting in a slight compression and/or expansion of one or both components (e.g. a cork in a wine bottle). This generates strong friction between the contacting surfaces, holding the components together. A well-known form of interference fit involved a frusto-conical protrusion being received in a conical depression.

Snap-fit

54. I need to cover this aspect of the common general knowledge in more detail because it is important on claim scope and on validity.

55. "Snap-fits" are a more sophisticated type of mechanical assembly arrangement than interference fits (although the two are not mutually exclusive as I will explain). They are ubiquitous in all sorts of consumer items such as pen lids, battery compartments, pill bottles, rucksack buckles, plumbing pipe clips and so on.

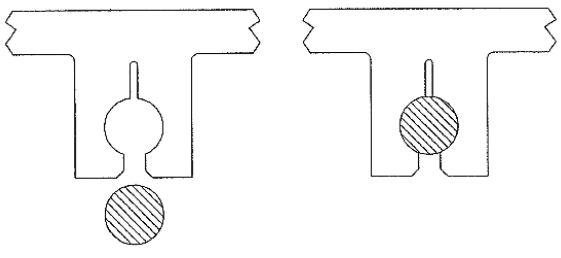
56. The essentials of snap joints are described in "Plastic Part Design for Injection Molding" by Robert A Malloy (1994) ("Malloy", introduced into the case by Mr Plascott in his first report and agreed to represent common general knowledge) as follows:

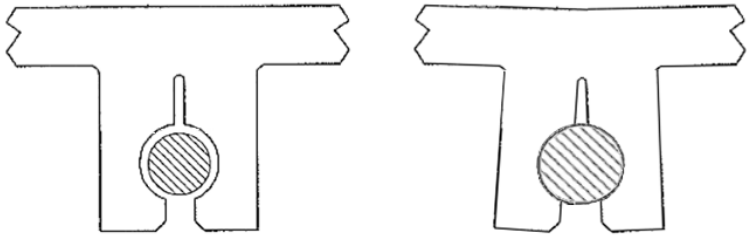
> "Snap joints can have a variety of geometries, however, the principles of operation remain the same in each case. When two parts are joined using the snap assembly process, a protruding feature on one component, such as a hook or beam, is deflected briefly during the product assembly operation due to an interference, after which the protruding part recovers elastically, and catches in an undercut or indentation on the mating component. The deflection during the assembly operation can be relatively large resulting in high stress or strain levels, however, once the assembly is snapped in place, the components are generally designed to be in a relatively stress free state (unlike press fits)…
>
> Snap joints are commonly categorized as (i) snap hooks or beams, (ii) annular or ring snaps, (iii) ball and socket snaps, or (iv) torsional snap joints. Snap joints are further categorized as being either separable or non-separable... Annular snap joints can be used to assemble rotationally symmetric parts. The annular snap joints shown in figures 6.9 to 6.11 represent common configurations…
>
> The most commonly used snap joint utilizes a cantilever beam that deflects and snaps into an undercut on the mating component. These cantilever beam snaps can be designed to be reversible or irreversible, and can be molded directly into the part at the desired locations. The cantilever beams are either an extension of the part walls (i.e. in-plane beams), or extend up (most commonly perpendicular) from the nominal wall (i.e. out-of-plane beams). A variety of cantilever beam configurations are shown in Figures 6.14 to 6.24."

57. In the text just quoted Malloy says that following recovery ("once the assembly is snapped in place") the components are "generally" designed to be in a "relatively" stress free state "(unlike press fits)".

58. What one takes from this is that it was known for components to be in a somewhat stressed state after assembly. This did not appear to be in dispute between the experts and I find that it was common general knowledge.

59. Some examples will illustrate this further (taken from the report of Mr Shi-Nash):





60. In the first example, reproduced directly from Malloy figure 6.22 (and showing the connection before and after mating) the components fit snugly and the arms that receive the cylindrical component are not stressed, or stressed only minimally. In the second (as with the third this was prepared by Mr Shi-Nash and is shown only after mating), the connection is looser and there is room for the components to move relative to one another which may be desirable but can have the side effect that there may be rattling or a sense of looseness. In the third, the cylindrical component is larger than the aperture provided by the receiving arms and those arms will be stressed when the components are assembled, because they will only partly recover. As I said above, I find (and I do not think it was really disputed) that having components stressed after mating is still a recognised common general knowledge type of snap-fit, but may also result in a degree of interference fit, as is the case in the third example above.

61. In snap-fits, the recovery of the components on assembly may cause a tangible and/or audible snap or click. This can be useful because it provides feedback in the factory and/or to the end-user that the components have been properly mated.

62. Snap-fits can be reversible or irreversible, depending mainly on the angle of incidence of the mating faces of the components (see figures 6.15 and 6.16 of Malloy).

63. The way in which the components deflect and recover in snap-fits depend on many factors, including the shapes of the components, their sizes and thicknesses and the materials used (and since the two components may be made from different materials, their relative deformability is also important). The recovery on assembly may be faster

or slower depending on those factors. But the absolute amount of deflection may be small: well under a millimetre in a pen lid for example.

Bonding

64. Adhesives are versatile and have many advantages over other assembly methods such as the ability to join dissimilar materials, the ability to compensate for thermal expansion mismatches with flexible adhesives and the ability to be used with thin, flexible substrates. They did not form any significant part of the argument at trial.

Connections between specific elements of masks

Cushion to frame

65. This was typically a non-permanent connection so that the frame and cushion could be detached for cleaning and replacement. The main requirement is that the connection does not allow leaks and forms a robust connection such that the cushion and frame remained attached during use. One type of connection whose use was common general knowledge in this context was a snap-fit, as I have mentioned above.

Frame to air supply

66. The frame needs to have an interface for the tubing. The frame is generally connected to the hose via an elbow assembly (as described above). The main consideration for this type of connection was again to ensure minimal leak between the components whilst also enabling relative movement (as discussed within the context of the elbow assembly above).

Issues on the common general knowledge

67. From the written evidence, there were two main issues on the common general knowledge.

68. The first was the extent to which the skilled team would be familiar with or find out about existing CPAP masks or other masks during a CPAP mask design project. ResMed's position was that the skilled team would know the essential features of the commonly used CPAP masks in the UK and might research other CPAP masks if a

particular need arose. FPH argued that the skilled team would undertake a review of existing CPAP masks and also look into other types of mask such as pilot masks, anaesthesia masks and many others, as Mr Shi-Nash had done himself.

69. As I have already said, I thought the only real impact of this was whether the skilled team would have known as a matter of common general knowledge about the use of snap-fits to connect components in CPAP masks. This was accepted to be common general knowledge for connections between cushion and frame, and more broadly it was accepted to be common general knowledge to use snap-fits to connect plastic components.

70. Lest I have overlooked some lingering relevance of this point, my finding is that the skilled team probably would review the CPAP masks on the market, but given the many different designs and their differing market penetration and geographical spread, that does not make any specific masks common general knowledge other than the best known ones that ResMed accepted. I do not think that the skilled team would as a matter of common general knowledge take inspiration from non-CPAP masks – there were plenty of CPAP masks to consider.

71. The second disagreement was on the complexity of CPAP mask design. Mr Plascott said that CPAP mask design is difficult, complicated and lengthy, and that as a result the skilled team would be very slow to change any one component for fear of causing an unpredictable knock-on effect on some other part of the design. Mr Shi-Nash said that CPAP mask design was relatively simple.

72. On this issue I agree with Mr Shi-Nash. I thought that Mr Plascott's stance was significantly overdone. Further, while no doubt it is true that actually bringing a CPAP mask design to market could take a couple of years, much of that time would be occupied with details such as choosing precisely the right grade of silicone, or designing tooling. Those matters have nothing to do with the level at which the 258 patent operates.

73. A matter related to this second disagreement is that ResMed argued that it was not common general knowledge to include a shroud of the type found in the 258 patent in a CPAP mask design, which is true. But ResMed sought to take this further and to say that when the skilled team encountered the shroud idea in the cited prior art, its lack of

familiarity with the concept would make it nervous and uncertain as to how to proceed. I do not accept this. The presence of the shroud merely requires joining two plastic components together and the skilled team would have no reason not to apply their common general knowledge to that task, or any reason to think that it would be unduly difficult or problematic.

CLAIM SCOPE – THE LAW

74. The main dynamic in this case is, as is not uncommon, that the patentee, ResMed, is arguing for a narrower claim scope to avoid the prior art, and FPH is arguing for a broader claim scope. There is one relatively unimportant exception concerning infringement of claim 2 where ResMed is arguing for a broader scope.

75. Since the decision of the Supreme Court in *Actavis v. Eli Lilly* [2017] UKSC 48 it may be preferable to refer to "claim scope" rather than to "claim construction", to indicate that (at least for the purposes of deciding whether a claim extends to equivalents in relation to infringement) it is no longer permissible to use the one-stage purposive construction familiar from *Kirin-Amgen v. TKT* [2005] RPC 9. That is not to say that the exercise does not involve interpreting words, of course.

76. The Supreme Court in *Actavis* decided that the exercise of determining claim scope for a variant, should (as a guideline, not a straitjacket) be approached by asking three questions (at [66]):

"*i) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent?*

ii) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?

iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

In order to establish infringement in a case where there is no literal infringement, a patentee would have to establish that the answer to the first two questions was "yes" and that the answer to the third question was "no.""

77. Of course, these questions have to be considered in the context of the Court's judgment as a whole, and in particular the third question has to be read in the light of [65].

78. The overall exercise for the Court is, therefore, first to determine what the "literal" (also referred to by the Supreme Court as the "normal") meaning is, and only move on to the three questions if the variant is not within it.

79. At one point in his oral opening Mr Purvis suggested that the parties (or at least FPH) had been proceeding on the basis of purposive construction alone (i.e. purely *Kirin-Amgen*), with the implication that I should do the same. I did not think that was a satisfactory way to proceed and asked for fuller submissions directed to the application of *Actavis,* which were provided.

80. In the end, and especially in the light of the decision of Arnold J in *Generics v. Yeda* [2017] EWHC 2629 (Pat) (given after the oral argument in the present case, and referred to below), I do not think it would have made any difference if I had applied *Kirin-Amgen,* but I remain of the view that it was appropriate to consider and apply *Actavis*, which is now the law. I also think it is not a legitimate approach simply to consider what would happen under *Kirin-Amgen* and then ask if and how *Actavis* changes the position.

81. Two particular issues about *Actavis* came up in the argument:

    (1) Does the exercise of identifying the "literal" or "normal" meaning, prior to any application of equivalents, involve purposive construction, or is it limited to a more truly "literal" approach? The parties both submitted that it was the former.

    (2) Can a claim be anticipated by equivalence, i.e. is a claim invalid if it would cover something in the prior art that is outside the "normal" meaning, but would (if done after grant) infringe only by the application of the *Actavis* questions? Prior to *Actavis* the established law was that claim scope must be the same for validity and infringement. FPH submitted that remained the position, which would mean

there could be anticipation by equivalence, and ResMed did not really dissent (although it said on the facts that FPH had not adequately developed any such case).

82. Arnold J considered both questions in *Generics v. Yeda*. He answered them as follows:

(1) Prior to considering equivalents, the Court must apply purposive and not literal construction ([135] to [139]). That is what the parties before me submitted.

(2) There cannot as a matter of law be anticipation by equivalence ([161] to [167]). That is contrary to what FPH submitted before me.

83. Both these important points are arguable and I expect will be considered by the Court of Appeal and possibly the Supreme Court in due course, but I consider that as matters stand I should follow the approach of Arnold J (although on the second point his reasoning was brief and *obiter*, since he held the patent invalid for obviousness).

84. I considered whether I should give the parties and especially FPH (who had argued for it) the opportunity to make further submissions on anticipation by equivalence in the light of *Generics v. Yeda*, but as will appear below the point is of no material significance to my overall conclusions, and FPH has succeeded overall for a number of other reasons.

85. In case this matter goes further, I will try to indicate what I think the truly "literal" meaning of the relevant claim features is (in the end I think it coincides with the purposive meaning) and I will indicate what I would have decided on anticipation by equivalence on the facts to the extent it might have arisen.

86. I consider that at all stages in the *Actavis* approach (including determination of the normal meaning) the Court should have regard to what the invention is. *Actavis* makes clear that this determination is not limited to what is in the claims and may involve consideration of broader teaching in the specification where the patentee asserts what has been accomplished. This may not be an easy exercise (and it was often difficult under *Improver*), but in the present case I have to determine the invention largely from the claims for purely practical reasons, because the specification includes little or nothing of significance beyond a large number of consistory clauses and the preferred

embodiments. In identifying the invention I think I should pay attention to the two-part form of the claim, and assume that the invention relates importantly but not exclusively to the characterising part of the claim.

INVENTIVE STEP - THE LAW

87. I was referred by ResMed to the well-known decision in *MedImmune v Novartis* [2012] EWCA Civ 1234, in particular the judgment of Kitchin LJ at [84]-[93]. Ultimately ([92-93], citing *Lundbeck v. Generics* [2008] RPC 19 at [24]) the court has to *"evaluate all the relevant circumstances in order to answer a single and relatively simple question of fact: was it obvious to the skilled but unimaginative addressee to make a product … falling within the claim"*. It *"must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success."*

88. I did not understand FPH to disagree with this.

89. These factors arise on the fourth step of the well-known *Pozzoli* analysis, which I intend to apply.

90. Those are the general principles. There are other points relevant to this case.

91. First, in many cases motivation will be a very important factor, but not always (see *Terrell on the Law of Patents*, 18th Ed. 12-161 - 12-168). Sometimes, it will be uninventive for the skilled person or team to make a change to the prior art not in order to solve some concrete drawback or because there is a problem that demands a solution but simply because the common general knowledge includes a number of ways of doing a particular job, and it is a matter of indifference which is chosen. This is often referred to as a "workshop modification" and it arises in this case.

92. Second, I bear in mind that there may be multiple obvious steps to take (see Laddie J in *Brugger v. Medic-Aid* [1996] RPC 635, 655). Merely because they are numerous does not mean that they are not obvious.

93. These two principles have to be scrutinised carefully, because they can be an all-too-easy way to cover up for an obviousness case which is weak because it lacks a basis in motivation and which involves selecting one approach from many possibilities. It all depends on the circumstances.

94. Finally, in some cases, a patent claim (or a main claim and a dependent claim) can cover two entirely unrelated ideas, features which have no dependence on one another and which do not combine to achieve a result. This is sometimes called a "sausage machine" claim (where the meat grinder and the filler are arranged in sequence but otherwise have nothing to do with each other), and was considered by the House of Lords in *SABAF v. MFI* [2005] RPC 10, and see *Terrell*, 12-193-12-197. In such a case it may be appropriate to consider each idea separately.

THE 258 PATENT

95. The 258 patent is entitled "Mask System". It was filed on 27 February 2009 and has a priority date of 4 March 2008.

The description

96. The description of the 258 patent is a little unusual in two ways.

97. First, it has no general explanation of what it is said to accomplish or of the central invention(s).

98. Instead, second, the section entitled "Summary of the Invention" consists only of numerous consistory clauses.

99. Following that Summary there is a "Brief Description" of the 45 figures, followed by a detailed narrative of the preferred embodiments. In places there are statements of the advantage of individual features or figures.

100. This all makes it rather difficult to discern any underlying or unifying purpose. Little context is provided to appreciate the goal. It is true that paragraphs [0002] to [0004] provide a very high level statement of what CPAP is and does, and identify comfort, fit, efficacy and compliance as important aspects of CPAP masks, but this is too general to be useful.

101. There are also two prior art citations mentioned at [0004], but the bare acknowledgments do not assist in understanding the objectives of the patent.

102. I do not suggest that this approach to drafting is wrong or necessarily undermines the validity of the patent or makes it more vulnerable to the prior art; the question is still whether the claims extend to something old or obvious. But the lack of explanation of the goal(s) does make the exercise of determining claim scope more difficult.

103. It would be burdensome to go through all the relevant figures in one extensive narrative, so to make this judgment more readable I will just explain the arrangement of certain key components and illustrate others by reference to some of the drawings. I will then pick up individual paragraphs when I come to determine claim scope.

104. A high level illustration of the main components can be gained from Figure 3, a coloured version of which was prepared by Mr Shi-Nash. I include the uncontroversial parts of his narrative:

"175. *The mask system described in the patent can best be summarised by reference to Figure 3, which shows an exploded view of the various components:*

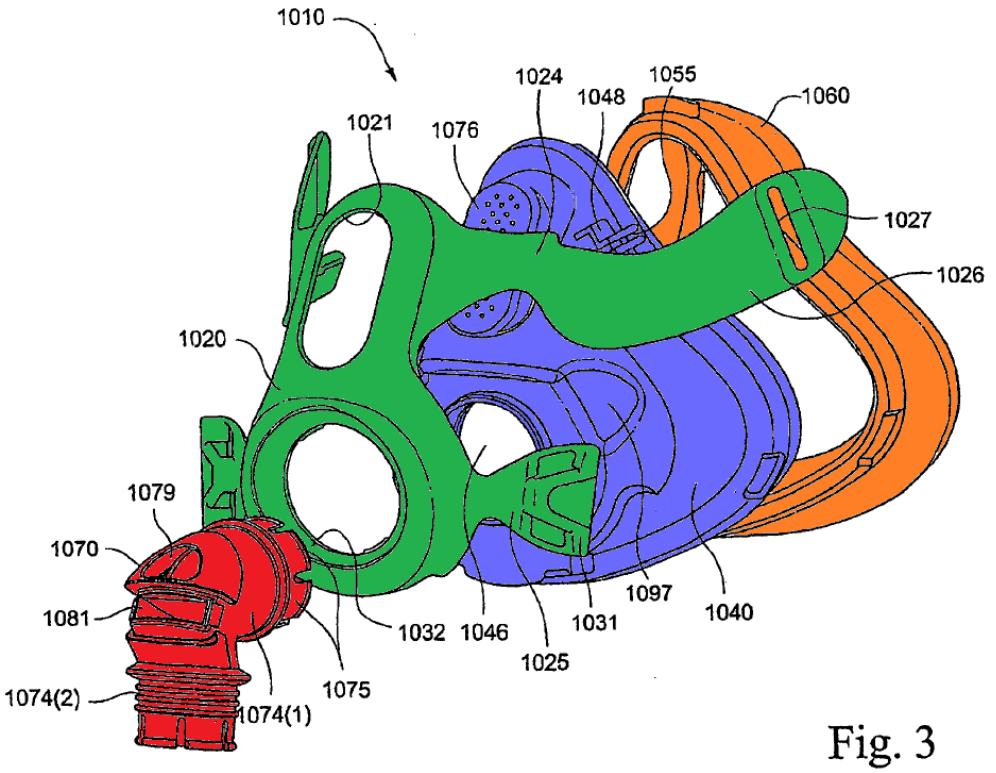


Fig. 3

176. Starting on the far right in Figure 3, there is a cushion (1060), which attaches to a frame (1040). The cushion is constructed from a soft and flexible material such as silicone. The cushion is described in more detail in section 3.1 of the patent and may also include a concertinaed section to provide increased flexibility and adaptability (Section 3.4 and Figures 30-33).

177. The frame defines a breathing chamber. The frame is constructed of a more rigid material than the cushion. The frame includes an opening (1046) to allow it to communicate with the elbow (1070). The frame also includes a vent (1076) for gas washout.

178. The shroud (1020) is connected to the frame and serves to attach the headgear to the mask. According to [0018], the shroud provides headgear connection points for the headgear to be positioned and arranged to stably maintain the mask in position on the patient's face. .....

179. The shroud is made from a resilient material, such as plastic, nylon or polycarbonate, etc. The top end of the shroud has an opening (1021) to accommodate the vent on the frame. The bottom end of the shroud also has an opening (1032) to accommodate the elbow, which opens into the frame. Upper headgear connectors (1024) extend from each side of the top end of the shroud and lower headgear connectors (1025) extend from each side of the lower end. As described in [0034], the benefits of having a separate shroud are said to be that it allows different materials to be used for the frame and shroud, allows the frame to be free of lower clip receptacles, allows the shroud to be used with different frame sizes and allows the shroud to be designed to minimise obtrusiveness of the mask system.

180. The headgear, not shown in Figure 3, may be removably attached to the headgear connectors on the shroud. Figure 9 shows an illustrative headgear which has both upper and lower straps which connect to the upper and lower headgear connectors on the shroud respectively.

181. Finally, there is an elbow (1070), constructed of a relatively hard material such as polycarbonate, with a first end (1074(1)) to interface/attach to the frame, and a second end (1074(2)) to connect to an air delivery tube."

105. An overall point to appreciate (which would occur to the skilled reader) is that at this high level the CPAP masks of the 258 patent differ from the common general knowledge in having the shroud (coloured green). It is a component additional to the common general knowledge, in which the headgear generally attached directly to the frame.

106. The presence of the shroud means that it has to be fixed to the frame in some way. This is where the snap-fit and snap fingers of claim 1 come in. Additionally, the elbow has to pass through the shroud to the frame and be connected to the rest of the components.

107. It is then useful to be able to see an example of the snap fingers of claim 1 and how they cooperate with the frame. This can be seen from figures 11, 14 and 21 (these are taken from the report of Mr Shi-Nash whose generally very useful colouring went slightly adrift in that figures 14 and 21 both show the shroud, from front and back respectively, but are coloured differently):

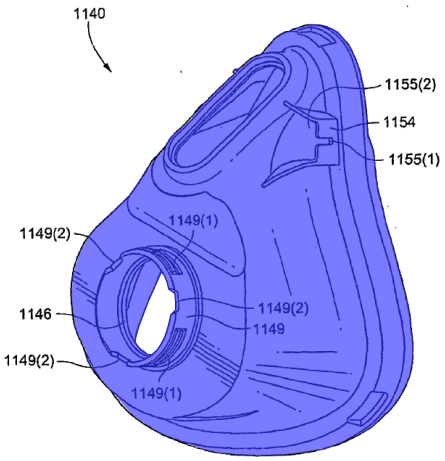


Fig. 11

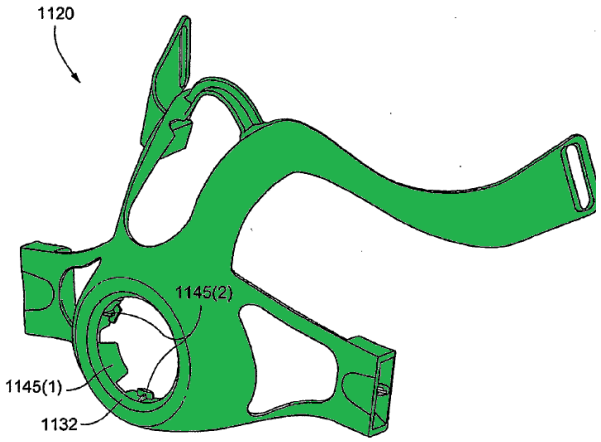


Fig. 14

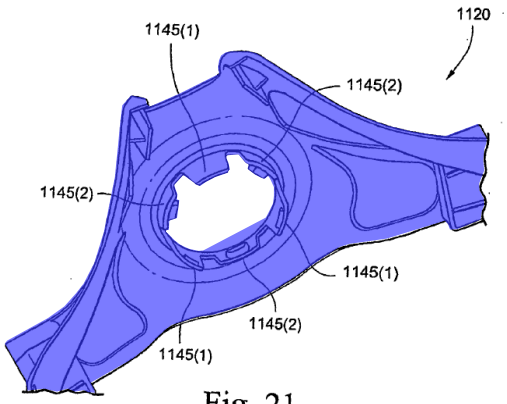
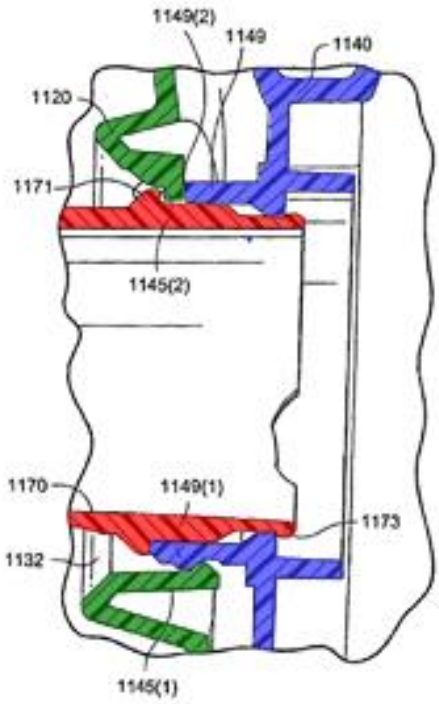


Fig. 21

108. The snap fingers are item 1145(1); they are stubby trapezoids. Note that item 1145(2) which also might look like a "finger" at first glance is actually a sandwich tab used in the retention of the elbow. A useful coloured section drawing of the elbow (red), shroud (green) and frame (blue) as assembled was prepared by Mr Shi-Nash from Figure 23:

Elbow attaches to breathing hose on this side



Patient's face on this side

Fig. 23

109. I also reproduce figure 22 at this stage because it illustrates a section through the shroud and frame:

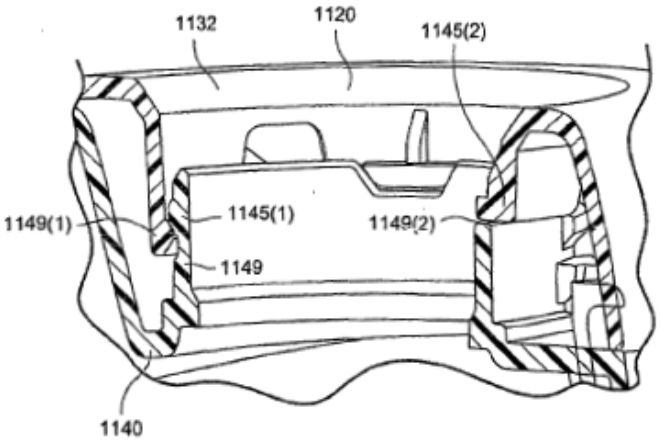


Fig. 22

110. There is what the parties accepted was an obvious error in the numbering: 1149(1) should be 1145(1) and vice versa. This drawing was relied on by FPH as showing that the snap-fit need not be very "snappy", which it derived from the fact that the mating faces of the finger and collar protrusion are at a relatively gentle angle to one another.

111. Finally as to the drawings, both parties made submissions on Figure 24, which is as follows:

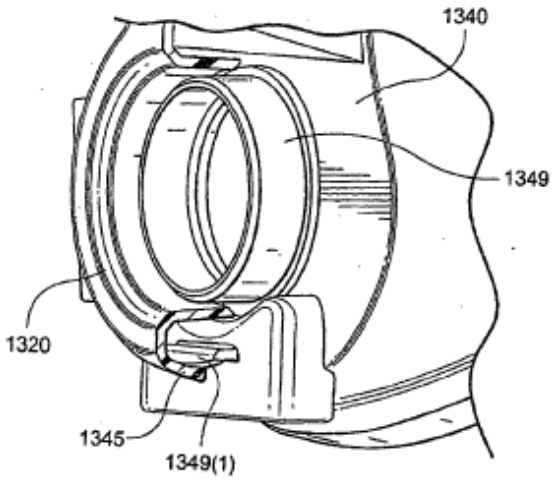


Fig. 24

112. The relevant description is at [0118].

113. The point about Figure 24 is that the "finger" 1345 on the shroud engages with the protrusion 1349(1) on the frame. But the finger appears to be annular, and this would seem inconsistent with the "finger" feature in the claim being intended to exclude annular snap-fits. I found all this rather inconclusive (and it was not explored with the experts), but one possibility is that although there is an annular feature it only has an engaging protrusion where it meets the tab. It perhaps provides a little support for FPH's position on Geist that the "finger" does not have to be separate, and generally that a wide variety of geometries may be "fingers".

114. From all the various figures I think that the skilled reader would appreciate the purpose of the shroud as being to give a different way of attaching the headgear.

Claim 1

115. Broken into integers, and omitting numeric references, claim 1 is as follows:

1(a) A mask system comprising:

1(b) a frame defining a breathing chamber;

1(c) a cushion provided to the frame and

1(d) adapted to form a seal with the patient's face and

1(e) a shroud provided to the frame and

1(f) adapted to attach headgear;

1(g) wherein the frame includes a collar surrounding an opening adapted to communicate with an elbow

1(h) wherein the shroud is characterised in that it includes a retaining mechanism

1(i) structured to establish a positive connection between the shroud and the frame

1(j) and the retaining mechanism includes one or more snap finger

1(k) structured to engage the collar with a snap-fit.

"Snap-fit"

116. ResMed submitted in opening that this term means:

> "*A protruding feature on one component being deflected briefly during the product assembly operation due to an interference with a mating component. Once pushed far enough to overcome the force created by the deflection, the protruding part makes a sudden elastic recovery and catches on the mating component. This sudden recovery creates a 'snap', providing a tactile and/or audible confirmation of engagement*."

117. And it also said that "*the snap-fit engagements shown in the patent are reversible, consistent with the notion of modularity described in the specification*".

118. By closing it had dropped the requirement for audible confirmation but maintained that there had to be tactile confirmation. I was unable to see the logic to this division and I think it undermines the point generally.

119. By contrast, FPH submits:

> "*One component is pushed over another, and the interference between them causes the temporary deflection of one or more elements on one or both components. As the interference stops or reduces, the deflected element(s) recover (either partially or fully) elastically into a mating engagement. There is no requirement for any kind of audible or tactile confirmation of attachment – neither as a matter of wording or as a matter of purpose (the claim covers permanently attaching the components in a factory, where no such confirmation would be required).*"

120. There is obviously significant agreement. The disagreement relates to ResMed's assertion that there be sudden "snap" recovery with tactile confirmation, and possibly reversibility, and to FPH's contention that there need only be partial and not necessarily full recovery (and concomitantly some residual deformation).

121. Although it is not a dictionary as such, I think Malloy gives firm and useful guidance here. I have referred to relevant passages above. What emerges is that the author uses the term to denote just the same as FPH, including the possibility of some residual stress (and hence deformation). I think this is the correct literal meaning (so far as one is needed) and how it would be understood in the art.

122. By contrast, the additional requirements urged by ResMed may be possessed by some snap-fits, but are not inherent to all snap-fits. There may or may not be a sudden snap, there may or may not be audible or tactile confirmation and the snap-fit may or may not be reversible.

123. The context of the specification does not assist ResMed's case in my view. For example, I was not referred to any text in it mentioning, let alone requiring, tactile confirmation (and e.g. in figure 22, as FPH said, there may well not be sudden, "snappy" engagement, since the mating faces are sloped). So ResMed's position is not even an attempt to read features from the preferred embodiments into the claim; it is an attempt to restrict the claim with features that are not spelled out in the preferred embodiments.

124. Nor can I see why it would make a difference to the purpose of the invention whether the snap-fit was, for example, sudden, or why the patentee would have desired to exclude from the scope of the claims arrangements in which the snap-fit was not sudden but still held the shroud to the frame. As to the former, doing the best I can I identify the purpose of the invention as being a way of holding the shroud to the frame by the particular means of a snap-fit, and specifically one using snap fingers. What is important is holding the components together in use, not the fine details of what happens while they are being mated.

125. At points it seemed that ResMed was arguing that the snap-fit must be formed in a front-to-back orientation (a point which would assist against Geist). I was not clear if this was ultimately pursued but if it was I reject it. As with the other points above it might be so, and is so in the examples, but there is no reason (or words) that it must be.

126. Finally, I should deal with a nuance of the way that Malloy expresses itself. It says that "a protruding feature on one component, such as a hook or a beam, is deflected briefly". ResMed effectively reads this as saying that where the protrusion is in fact a beam, the beam must deflect (and this point also forms part of ResMed's argument on "snap fingers"). I think this is reading too much into Malloy, which is just giving an example of a protrusion. It does not exclude other kinds of protrusions, and nor does it exclude protrusions on both components, both of which may deflect (as the experts

agreed). The fundamental statement is that there has to be a protrusion (or more than one) which deflects, and that would be the common general knowledge view, too.

127. In summary, I conclude that the correct literal meaning is the meaning FPH advanced. The context of the specification is consistent with and supports this, so the normal or purposive interpretation would be the same as the literal meaning on the facts of this case in any event. I reject ResMed's attempts to narrow the meaning.

"Snap fingers"

128. ResMed submits that:

"Having regard to the common general knowledge and the specification …. the skilled person would understand a 'snap finger' to be broadly equivalent to the cantilever or beam type 'protruding feature' described in Malloy (as opposed to, for example, an annular snap-fit)."

129. It further said (if less explicitly) that it was a requirement of this feature that the finger must deflect during the temporary interference which happens as the snap-fit is made. In other words, that it is not enough if the other component flexes and the finger does not.

130. And it also said (in the context of Geist) that the finger must be able to flex independently of the component to which it is attached.

131. FPH says that:

"*Snap finger is not a term of art. It simply means that the mating engagement involves an identifiable protruding element. This is not required to have any particular shape or configuration (the so-called 'fingers' in the Patent are not shaped like 'fingers' – rather they look like trapezoid tabs).*"

132. I did not understand ResMed to say that "snap finger" required any particular ratio of length to width; or that they must be generally long and thin. I agree, and anyway for it to do so would be inconsistent with the preferred embodiments, and also with the FPH products infringing (since all have stubby trapezoid "fingers").

133. So when ResMed makes the link to the cantilever or beam type in Malloy I do not think it means in terms of proportion (and anyway I think the depictions in Malloy are quite possibly exaggerated in their proportions to make the deflections easily visible), but in terms of function.

134. Thus the parties were agreed, and I accept, that "finger" does not connote proportions as such.

135. I also agree with ResMed that "snap finger" is apt to exclude from the claims some of the well-known kinds of snap-fits such as annular snap-fits and ball-and-socket arrangements. I consider this is the most natural view of the feature: the skilled person would understand that what was being done was to exclude from the claim those other types (though it would not be apparent why). This fits with the view of the invention that I have taken above.

136. So to the extent it matters, I find that the literal meaning of "snap finger" is an identifiable protrusion which can form a snap-fit of the very generally beam type. It is not entirely comfortable to call this a "literal" meaning since it depends significantly on context, and is not in any sense a dictionary meaning. It would also be the purposive meaning, which is what matters.

137. I reject ResMed's argument that the finger must deflect. It makes no difference to the purpose of the invention whether it is the finger or the other component or both which flexes, and there is no reason to think the patentee intended a narrow meaning. In many cases it will no doubt be the case that the finger flexes but there is nothing in the language used or in the specification to say that it is a requirement (likewise the "independent flexing" requirement will also often be true but there is nothing to require it to be so).

138. ResMed accepted that figure 24 (referred to above) did not support its narrow interpretation, and sought to meet it by saying that that figure is ambiguous. I agree that it is ambiguous, but that merely tends to suggest that the precise shape of the finger does not matter, which is against ResMed.

139. ResMed positively relied on other passages from the specification. It said (closing skeleton, paragraphs 29-31):

"*29. With the exception of the ambiguous Figure 24, each of the remaining drawings explicitly shows a structure projecting from a wall parallel to the direction of engagement that is designed to be 'resiliently deflected by and then engage the mating surface, i.e. a classic cantilever or beam snap feature.*

30. It is relevant that the specification uses two other terms to describe protruding features which are involved in a snap fit: 'tang' and 'tab'. The term 'tang' is used in the specification to describe a variety of protruding features, some but not all of which are engaged in a snap fit: see [0093] and Figure 3; [0112] and Figure 17; [0113] and Figures 18, 19 and 20.

31. The term 'tab' is also used to describe a variety of protruding features, again some but not all of which are engaged in a snap fit. See [0044] and Figures 38.1-38.5; [0046] and Figures 39.1-39.6 [0099] and Figures 27-30; [0116], [0117] and Figures 14, 15, 17 and 21, 22, 23; [0131] and Figures 42.1-42.7. In some of these Figures, the precise nature of the 'tab' structure is unclear. However, where the nature of the structure is clear, the word appears to be used to describe a projection which is not designed to deflect. See in particular, [0044] and Figures 38.1-38.5; [0046] and Figures 39.1-39.6; [0116], [0117] and Figures 14, 15, 17 and 21, 22, 23."

140. I do not agree with paragraph 29: the drawings do not spell out specifically which components must deflect or how much.

141. I also did not find the references to "tangs" and "tabs" helpful. I cannot see why it matters that something serving a different function which is not designed to deflect (assuming that to be the case) is called a "tab" or "tang" rather than a "finger", or why that implies that a "finger" must deflect.

142. These points were also made without all the relevant parts of the specification having been explored in evidence with the experts. I am not confident as to what the tangs and tabs are there for, or what the skilled reader would infer about their operation and in particular how they may or may not deflect or deform in use. I do agree with the submission by ResMed that the nature of the "tab" structure is not always clear, but that hardly helps it.

143. I therefore agree with FPH's contention on this claim feature.

Claim 2

144. Broken into integers, and omitting numeric references, claim 2 is as follows:

2a The mask system according to claim 1

2b wherein the top end of the shroud is adapted to be positioned proximal to the nasal bridge region or nose of the patient and

2c the bottom end is adapted to be positioned proximal to the mouth or chin of the patient and

2d wherein the top end includes an opening to accommodate a vent arrangement of the frame and

2e the bottom end includes an opening to accommodate an elbow

The "top end" and "bottom end" of the shroud

145. This is the kind of construction point where it is best to say why it matters so that one can understand the question. It relates to infringement, and the point is that in the Simplus design there is a forehead support included in the one-piece moulding of the shroud. If the top end of the shroud is taken as being the upper end of the forehead support, it is not proximal to the nasal bridge region.

146. So, where is the "top end of the shroud"?

147. FPH says that it is simply the upper part of the component which is the shroud, and in the context of the Simplus that is the upper part of the forehead support.

148. ResMed says that the "top end of the shroud" is a region starting just below the vent and extending upward from there.

149. I was troubled by the fact that claim 9 (the forehead support) is dependent on claim 2 (or any preceding claim) and therefore the patentee appeared to have contemplated that it would be possible to have both a forehead support and the features of claim 2. Mr Purvis pointed out that the dependencies in the patent are (as is often the case) not well thought out, and he pointed to the difficulty of reconciling claim 9 with claim 6, on which it is also dependent, which I accept.

150. Nonetheless, I do not see why claim 2 should suddenly become impossible to perform simply because of the addition of a forehead support (or to put it another way, why figure 1B would cease to infringe claim 2 if a forehead support were added). So I do not accept FPH's position.

151. ResMed's argument is also rather clumsy because it has the result that, in a mask with a forehead support, the "top end" of the shroud is the great majority of it.

152. A refinement of ResMed's approach might be to leave out of consideration any forehead support if present, and I think this finds a little textual support in claim 9 which says that the shroud "is provided with" a forehead support, connoting that the forehead support is to be identified separately (even if moulded in one piece with the shroud). This leaves some room for dispute about where precisely the border between the shroud and the forehead support is, but I do not think that is a real problem since all one really needs to know is if the top end of the shroud is proximal to the nasal bridge and has a vent in it.

153. My suggested refinement is only a linguistic tweak of ResMed's approach and on either view there would have been infringement of claim 2 by the Simplus mask had the patent been valid. This is not really a literal meaning; I doubt whether a truly literal meaning of this feature is possible since although each word has a dictionary meaning, context and purpose are necessary to determine their combined effect.

"Protrusions"

154. This feature appears in claim 12.

155. ResMed contends that:

> *"As a matter of ordinary language, and consistent with the specification (see [0117] in particular), a collar which 'includes one or more protrusions' requires a distinct structure to protrude from the collar, rather than being satisfied by the basic shape of the collar itself."*

156. It also said that the protrusions must be there to play a part in forming or maintaining the snap-fit (relying on the further words of the claim that the protrusions be "*adapted*

to engage the respective snap fingers provided to the shroud", although this does not explicitly say to what purpose).

157. FPH contends that:

"*The purpose of the protrusion(s) referred to in claim 12 is specifically to engage the respective snap fingers. A protrusion is satisfied by any 'higher' area of the surface of the collar which creates a mating engagement with the 'finger' when it has snapped into place.*"

158. These contentions may at first sound like the parties were in agreement, but in fact they were not. The reason is essentially that although in a truly literal sense a protrusion might have to be something that identifiably juts out from the surrounding surface, FPH's contention was that a smooth, curved surface could as a matter of purposive interpretation be considered to have protrusions. This can best be explained in context, which is the allegation of anticipation of claim 12 by Geist.

GEIST

159. Geist is a United States Patent application published on 2 March 2006.

160. It discloses a nasal (i.e. covering the nose only) CPAP mask.

161. Both sides referred to figure 2A, and I reproduce here the coloured version provided by Mr Shi-Nash:

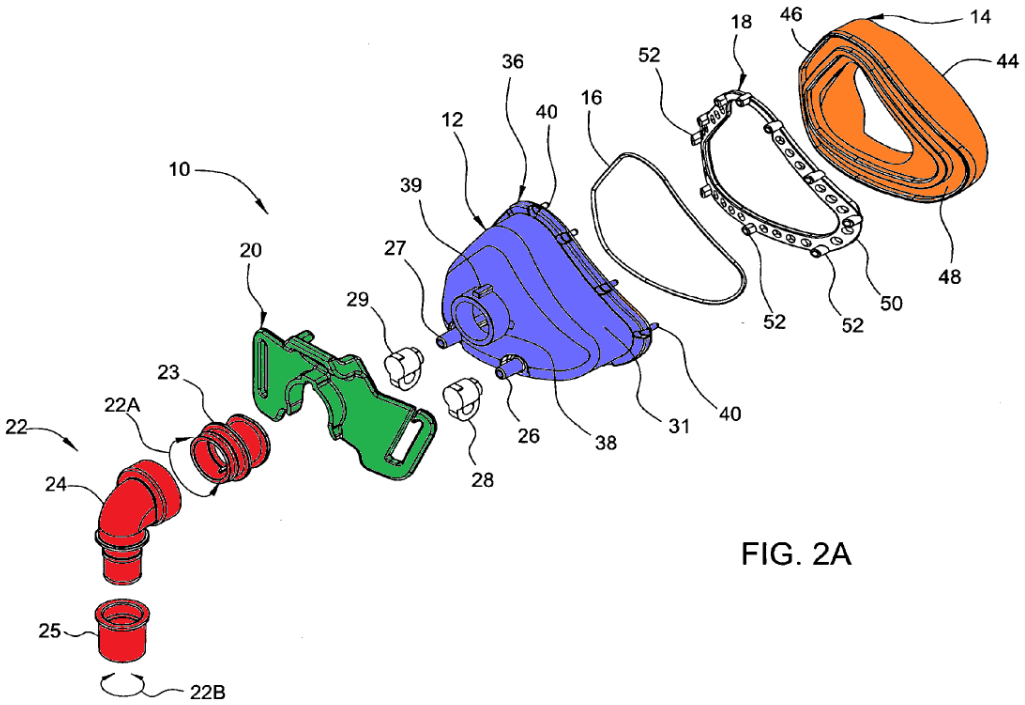


FIG. 2A

162. Mr Shi-Nash described this as follows, in paragraph 192 of his first report:

"In summary, there is a mask shell (12), which connects (via parts 16 and 18) to a mask seal (14) (i.e. the cushion). A headstrap retention bracket (20) attaches to the mask shell, and a dual swivel configuration (22) allows connection to a gas supply hose (not shown)."

163. This is accurate and uncontroversial in itself, but it omits to explain that item 16 is a malleable wire in the shell ("frame" in the terminology used in the 258 patent – I will use the words interchangeably here and in relation to Lovell) allowing the latter to be conformed to the user's face. ResMed relies on this to argue that the collar (also part of the shell) would also be conformable and so more yielding than the bracket 20. ResMed then says that the connection of the collar to the bracket will not be snappy enough to be a snap-fit (this is not the only point it makes, I emphasise).

164. To explain where Geist fits into the case generally, one should appreciate that, unlike the common general knowledge CPAP masks, the headgear does not attach directly to the frame but to an additional component 20, referred to as a "bracket" and which ResMed (belatedly if inevitably) had to accept was a shroud within the meaning of the 258 patent. This brings Geist close to claim 1 of the 258 patent; whether it invalidates

depends on the connection of the bracket to the collar: is it a snap-fit, and does it have snap fingers? Alternatively, would it be obvious to make it so?

165. An assembled version is as follows:

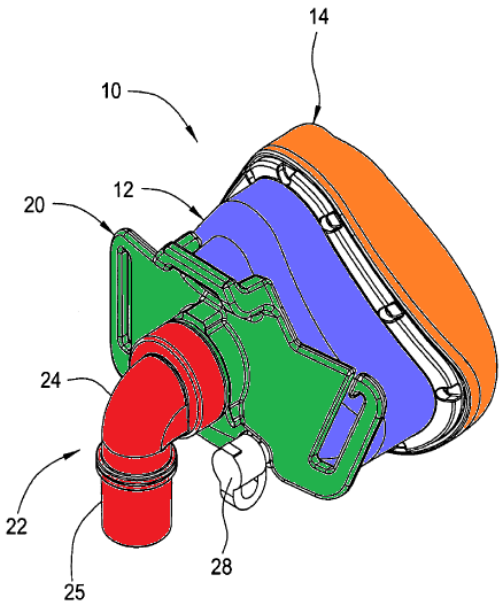
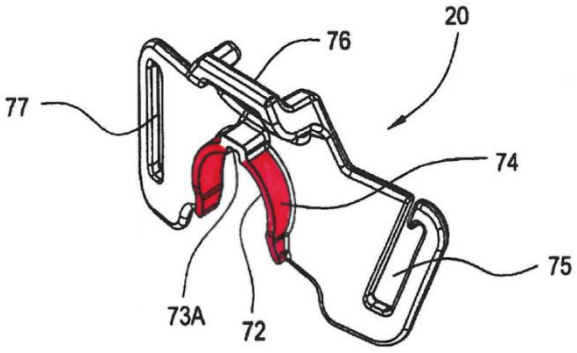


FIG. 1

166. And a depiction of the bracket alone, with the portions that are said to be "fingers" (coloured red) is as follows:



167. The alleged fingers are not separate from the rest of the bracket; there is no gap along the outside of the curving edge of item 74. The bracket has a notch at the top which cooperates with protrusion 39 on the collar to prevent rotation (rather than to prevent longitudinal separation).

168. In Geist, the fitting of the bracket (shroud) onto the collar is downwards (by contrast with the preferred embodiments of the 258 patent which are front-to-back). This is for the reason, which I think would be striking to the skilled reader, that the arrangement enables the user to pull the mask, elbow and attached hose down and away from the bracket, leaving the collar and headgear on the head. This enables the user to move away from the CPAP machine, for example to go to the lavatory in the night, without having to refit the headgear afterwards.

169. Geist describes the fit of the bracket to the collar as wedged or interference (see in particular [0042] and [0044]). ResMed understandably relies on this to say that it is not a snap-fit, and this is the teaching that I have said Mr Shi-Nash omitted to deal with satisfactorily.

170. So a first and important question is whether, despite this, what Geist describes is a snap-fit.

171. I understood it to be accepted by ResMed, and anyway I find it to be plain to the standard required for anticipation (clear and unambiguous), that the curved items 74 together form an arc of a circle subtending appreciably more than 180 degrees, i.e. more than a semi-circle. Accordingly, when they are forced down over the collar there is a temporary interference causing that arc to open, and it then recovers partially. In other words when the two components are fully mated, the result is analogous to the third example of snap-fits shown above at paragraph 59. This is no doubt why Geist calls it an interference or wedged fit: it is, but it is also a snap-fit, and I have found in relation to the common general knowledge that a fit can be both.

172. The tips of the items 74 grip the underside of the collar a little.

173. Another way of looking at this, which I accept based on the evidence of Mr Shi-Nash would be readily apparent to the skilled reader, is that the items 74 are like a plumbing pipe clip, albeit embedded in the bracket.

Novelty over Geist

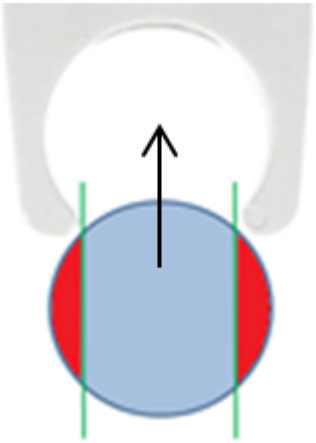
174. On the claim scope I have reached, Geist anticipates claim 1 of the 258 patent. The fit is a snap-fit with the characteristics I have described, albeit that it also has an

interference component. The items 74 are fingers notwithstanding their attachment along their length to the bracket/shroud. They are items whose shape is perfectly apt to be described as a finger, and given the range of generally stubby items in the 258 patent described as fingers it would be odd if they were not properly so to be described. Although attached along their length they are identifiably discrete parts of the bracket serving a distinct function (engaging and holding the collar). There is nothing arbitrary in their identification.

175. On ResMed's claim scope there would not be anticipation because there is not clear and unambiguous disclosure that the snap-fit involves a sudden return or tactile or audible feedback, or that the fingers deflect (it might be that the collar alone does). In addition, ResMed would rely on the fact that the items 74 are not separate. These matters all require an analysis of obviousness, which I deal with below.

176. Geist would, I think, not anticipate claim 12 on a truly literal meaning because it does not have protrusions on the collar, which is smooth and circular. However, FPH argued that it would anticipate on a proper purposive interpretation (the relevant standard), or as an equivalent.

177. FPH argues that the lower portion of the collar, where the ends of the items 74 grip, provide an angled surface against which the items 74 can push, holding the collar back into the recess in the bracket. The point was illustrated by a drawing provided by Mr Shi-Nash:



178. This plainly achieves the same object as "literal" protrusions which would cause a more abrupt change in the surface of the collar.

179. The areas shaded red are part of the cylindrical collar, but if one had started with a straight sided collar as shown in blue (which would not have protrusions on any view) and added the red parts one would have had no difficulty in calling them protrusions.

180. I find this convincing and hold that on a proper purposive interpretation Geist has protrusions and anticipates claim 12.

181. That makes it unnecessary to consider anticipation by equivalence, but if the above argument for some reason could not be accommodated within the rubric of purposive construction, or if the jumping-off point for the *Actavis* questions is the truly literal meaning, then I would have held that the same logic led to anticipation by equivalence, if the law permitted it.

182. It is because I find anticipation of claim 12 by Geist on purposive construction, plus the fact that I find it obvious over Geist and invalid over Lovell even on a narrow interpretation, that I consider the point of law about anticipation by equivalence of no material importance to my overall decision.

183. Geist is not said to anticipate claim 2, claim 9 or claim 14.

Obviousness over Geist

184. I have to consider obviousness of claim 1 on the basis that I am wrong on one or more of the points about claim scope, and I then have to consider claims 2, 9 and 14 separately.

185. I have found that it is not a requirement of claim 1 that the recovery of the snap finger be sudden, or that there be audible or tangible feedback, or that the fingers must deflect, or be separate. If they are requirements of claim 1 then they are not clearly and unambiguously disclosed in Geist, but that does not mean they are not obvious. It depends on what the skilled reader would think was likely from the disclosure and by what means it was obvious to implement it.

186. In *Pozzoli* terms, I have identified the skilled team and common general knowledge above (questions 1 and 2), and for claim 1 the differences (question 3) between Geist and the prior art are the matters I have identified in the preceding paragraph. Other than in relation to making the fingers separate, where FPH relied on positively changing Geist, the skilled team would have to make decisions of its own on these matters using its common general knowledge, Geist being silent.

187. Mr Shi-Nash and Mr Plascott disagreed about whether the collar or the bracket was more flexible or compressible, and each raised various points in support. For example, Mr Shi-Nash said that the fact that the elbow was inside the collar would tend to prevent it from being compressed while Mr Plascott (as I have mentioned above) prayed in aid that the member 16 allowing the moulding of the frame to the face, suggesting that the collar (which is part of the frame) was soft.

188. I felt these were all rather minor pointers. The essential fact of the matter is that Geist leaves these decisions to the reader. One of a range of obvious options, consistent with the materials generally used in CPAP masks, would be to design a collar which was rigid enough that the items 74 deflected and snapped into place relatively quickly. It being common general knowledge that an available advantage of snap-fits was audible or tangible feedback, it would be obvious to design that in even if it did not happen anyway. This is all classic workshop modification (or at least workshop choices, since this is an exercise in making initial decisions, not changing what the prior art provides).

189. In relation to the issue of whether the items 74 deflect separately from the rest of the bracket, a suggestion was put to Mr Plascott that it would be obvious to remove some of the material from the bracket at the lower ends of the tips of the items 74 so that those tips could flex independently. He did not agree that that was obvious (T2/332-334) and thought it was a bad idea for reasons which seemed sensible to me. The suggestion was not made in Mr Shi-Nash's evidence as far as I am aware. So I reject this argument, but it does is not matter on the view I have taken of the scope of "snap fingers".

190. Claim 2 requires a hole at the upper end of the shroud to accommodate a vent. Geist is not arranged this way because the vent is at the bottom of the frame (visible in figure 10). There was no dispute that if the vent was at the top of the frame it would be

necessary to provide a hole in the shroud to allow the vent to operate. So this is just an argument about whether it was obvious to put the vent at the upper part of the frame. This was one of a number of well-known options in CPAP masks and it would have been obvious from Geist, especially if its basic idea was implemented in a mouth-and-nose mask (which I find was also obvious) making more room for a vent at the top.

191. Because the vent in Geist is on the underside of the frame air would be directed away from the patient's eyes. It was put to Mr Shi-Nash that this was a benefit the skilled person would not want to lose. He replied that having the vent underneath would require tooling with pins in two different directions (to form the collar from the front and the vent from underneath) and that would be seen as a burden. I found this convincing and it is another example of a routine workshop modification being made for a relatively minor practical reason.

192. Claim 9 requires a forehead support and it is a claim to using a known common general knowledge item for its known common general knowledge purpose. Geist does not have a forehead support, perhaps because it is a nose-only device. In any event I hold that it would be obvious to use a forehead support to provide greater stability. Mr Shi-Nash's evidence to this effect was not really challenged.

193. Moreover, claim 9 is a sausage-machine claim. In itself, a forehead support is obvious but has nothing to do with the shroud attachment of claim 1. Mr Acland accepted this but said that the sausage-machine point had not been pleaded. That is true (although I would question the necessity to plead it when it was merely the common general knowledge of forehead supports that was relied on, not a specific citation), but when I asked him what point of substance could have been raised if it had been pleaded he frankly and rightly said there was none.

194. So I would have found claim 9 obvious on that basis too.

195. Claim 12 is the claim which requires protrusions on the collar. I have found this anticipated on a proper purposive interpretation of the claim but if I were wrong I would still hold the claim obvious on the basis of Mr Shi-Nash's evidence in his second report that more distinct protrusions would be an obvious equivalent.

196. Claim 14 is to co-moulding the frame and cushion. This again is a common general knowledge technique applied for its known purpose. Mr Shi-Nash said it was obvious and I accept his evidence, which was not materially challenged. Mr Plascott pointed out that Geist teaches a cushion which is reversibly attached to the frame, but that cannot overcome the fact that it was common general knowledge to co-mould them.

197. This is classic, routine workshop modification.

198. Claim 14 is also a sausage-machine claim and I would have found it invalid for that reason as well.

LOVELL

199. Lovell is a European Patent application published on 6 December 2000.

200. It is similar to Geist in its overall conception: a nasal CPAP mask having the usual main components known from the prior art, plus a retainer (which would be called a shroud in the language of the 258 patent) for the attachment of straps.

201. I mention the similarity of Lovell to Geist not in order to combine the teaching of the two documents, which would not be legitimate, but in order to avoid repeating the separate arguments at length when they are the same.

202. Mr Shi-Nash prepared a coloured version of Lovell using the same colours for the principal components:

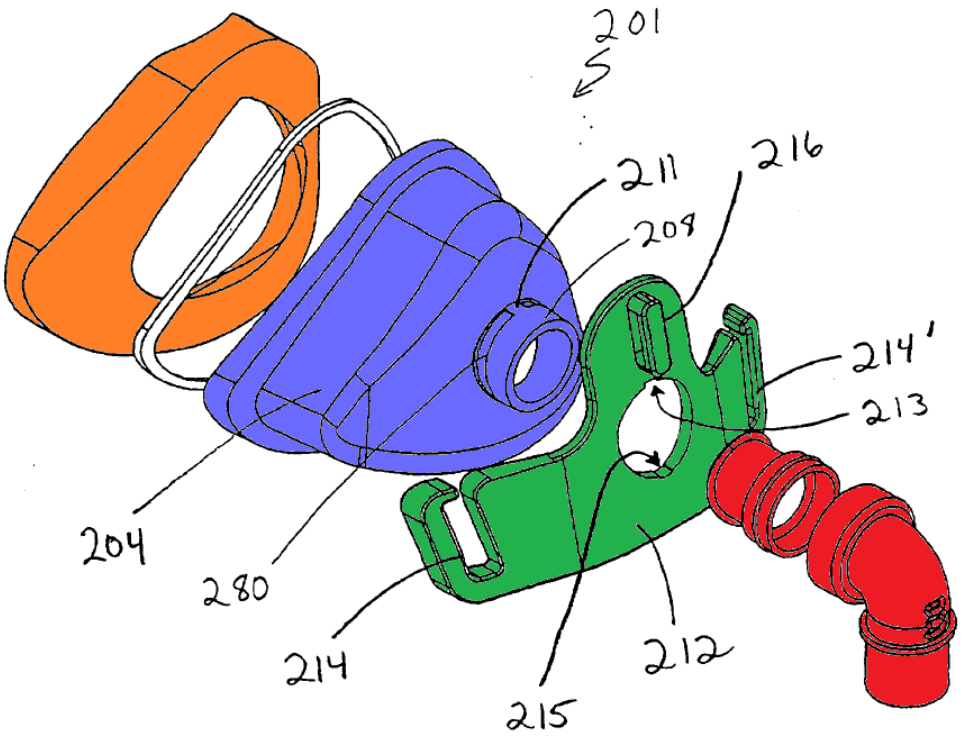


FIG. 10A

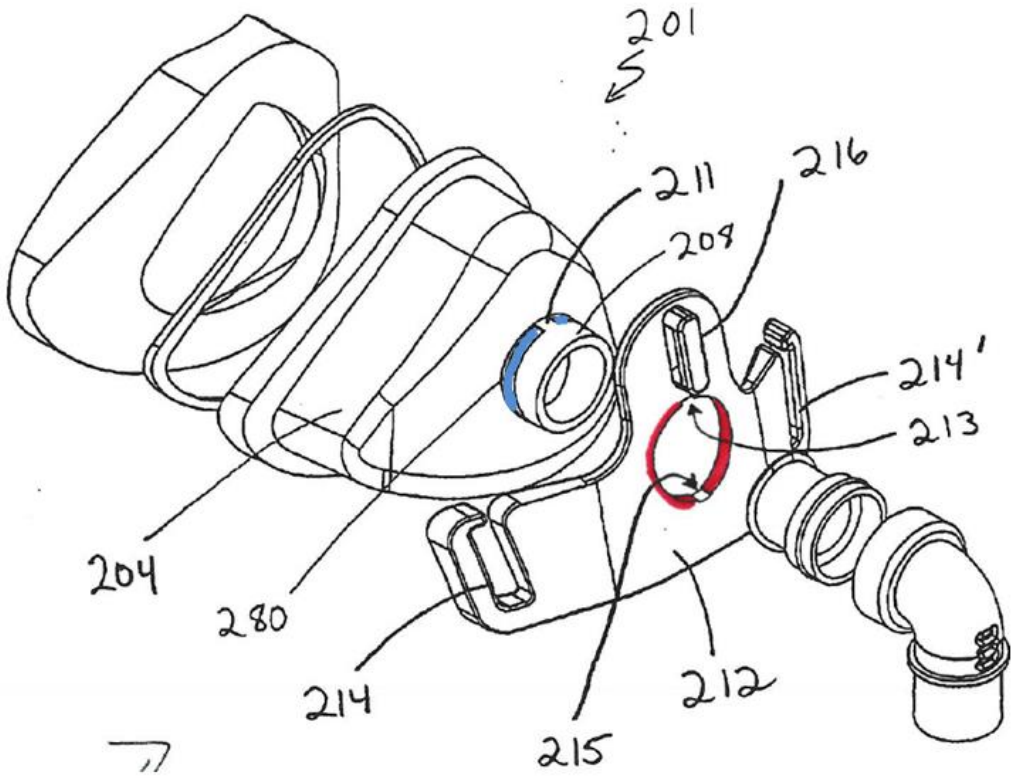
203. This includes but does not emphasise or colour the malleable member (between the orange cushion and the blue shell) which allows moulding to the face in the same way as with Geist. Accordingly, ResMed makes the same argument that the shell and the collar it bears is likely to be more compressible than the retainer.

204. Lovell also involves a special arrangement for the cushion (not shown above) of using a gel-filled bladder, and ResMed says that this would deter the skilled team from using co-moulding, which is said to go to the obviousness of claim 14.

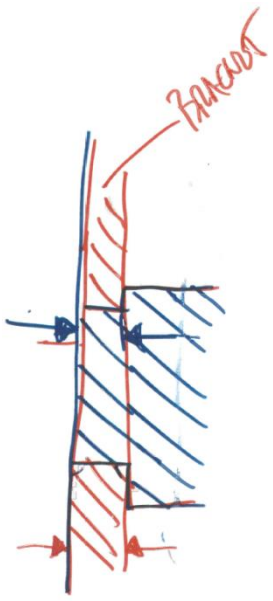
205. Since Lovell has a shroud and the other main components of claim 1 of the 258 patent, the argument (as with Geist) was all about the nature of the connection of the shroud to the collar.

206. The connection is achieved by cooperation of features on the profile of the inner circumference of the hole in the retainer (coloured red in the following drawing

prepared by Mr Shi-Nash) with two parts of a near-circular annular depression where the collar meets the frame (coloured blue):



207. Slots 213 and 215 line up with tabs 211 and 211' and once the retainer is in place they prevent the retainer rotating relative to the frame. The two red protrusions engage with the two blue near-semi-circular depressions. After some discussion in the evidence, it became common ground (if not already) that the red protrusions fill the blue depressions so as to press on their front, back and side walls, as shown in the following drawing done by Mr Shi-Nash during cross-examination:



208. When I say "red protrusions" I do not mean that they protrude beyond the front or back surfaces of the retainer. They protrude inwardly in a circumferential direction on the inner surface of the hole in the retainer.

209. As to how the red and blue features behave when the retainer is put onto the frame, it was common ground that they have to deform relative to one another, but there was a dispute as to which deformed more, and whether the red features deformed materially at all. It was also common ground that once the red features had reached the blue depressions the components would recover relative to one another. There was a dispute as to whether the inlet (collar) 208 was tapered; I do not think it matters, but in case it does I find that while it would be obvious to taper it to assist with fitting the components together, it is not clearly and unambiguously disclosed.

210. So as with Geist, Lovell discloses a fit which is both an interference fit and a snap-fit (in the sense I have identified above). Lovell contains explicit statements referring to the interference fit (see [0044]), but does not in terms refer to any snap-fit (and Mr Shi-Nash again omitted to point this out). Nonetheless, I hold that it is clear and unambiguous that there is a snap-fit in the relevant sense, that the components undergo deformation during temporary interference which recovers when the components are in their mating position. The skilled reader would see the fit as a snap-fit and an interference fit; this would not be at all surprising to them since that was a common general knowledge way of attaching two pieces of plastic to each other.

211. ResMed barely (if at all) disputed this view of what must happen, but maintained that the fit could not be a snap-fit if it was an interference fit. However, those are not mutually exclusive. As I understood it, ResMed also argued (though perhaps somewhat faintly) that such recovery was not sufficiently sudden or "snappy". Again, this is not a requirement of the claim.

212. ResMed also challenged whether the red protrusions are "snap fingers". The two points taken were that they do not protrude above the surrounding surface of the retainer and that they do not deform when the retainer is pushed onto the collar. However, neither of these is relevant to whether they are "snap fingers" on the claim scope I have determined. In relation to the first, I have said above that they do protrude, just radially instead of axially and I cannot see why that should matter.

Novelty over Lovell

213. This all means that Lovell anticipates claim 1 of the 258 patent.

214. I also consider that Lovell anticipates claim 12. ResMed said that there were no relevant protrusions because the elements 211 and 211' prevent rotation and do not contribute to the snap-fit so as to hold the retainer onto the collar. I accept this point, but the shoulder on the collar where there is a change of level from the depression to the main, thicker cylindrical section is a protrusion and it keeps the snap-fit in place. There is anticipation for that reason. I do not think ResMed ever tried to meet this point.

Obviousness over Lovell

215. I turn to obviousness.

216. The *Pozzoli* framework for Lovell is essentially the same as for Geist, except that the red elements alleged to be the snap fingers are already separate in the sense that if they flex they can do so separately from the rest of the retainer.

217. First, for the same reasons as I gave for Geist, I think it would be uninventive to choose materials for the retainer and frame which led to a (more) sudden recovery with tangible or audible feedback, and for the red protrusions to deflect. So if claim 1 requires any of those things there is no inventive difference. As with Geist, this is not

about changing Lovell but making sensible decisions where the document is not explicit.

218. Second, to meet ResMed's arguments about "snap fingers" requiring protrusion in a particular direction, or a particular shape or degree or direction of deflection, FPH argued that there are many kinds of snap-fit, and it would be uninventive to adopt ones which differed in minor ways from what is explicitly shown in Lovell.

219. Mr Purvis opened this attack by saying that this sort of making of a choice of snap-fit was "inherently obvious" because of the wide variety known in the common general knowledge such as Malloy.

220. I think this is too imprecise and I do not accept it as a legitimate way to attack a claim for obviousness. It is not enough on its own to say that there was a wide variety of approaches in the prior art. It may be a promising place to start but a party attacking a patent still has to show that it would be uninventive to land inside the claim. The claim in this case requires a snap-fit with snap fingers, not any kind of snap-fit, and it is necessary to show that choosing one with snap fingers would be uninventive (remembering that in the scenario I am considering now the claim scope would be as ResMed submits). After all, there might in theory have been some reason when one gets down to specifics that snap fingers would not be appropriate in the actual context of the prior art.

221. The excessive generality of FPH's position was also to be seen in Mr Shi-Nash's written evidence, in particular paragraph 222:

"222. In reaching this view, I am of course conscious of the fact that the two snap fingers coloured red do not look like typical fingers, in the sense that they do not 'poke out' above the surrounding surface of the retainer bracket. However, from a functional perspective, there's really no difference at all; they are still two protrusions which snap into complementary recesses. If I am wrong, and these weren't considered to be snap fingers, as I explained in paragraph 74 above, it was well known that snap fit connections could come in many different forms, shapes or positions, some of which would include a finger-like protrusion snapping into a complementary recess. The skilled person would certainly appreciate that the connection between the retainer and

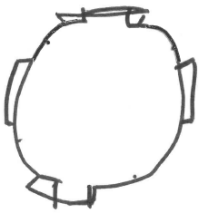
the frame could be easily re-designed with more finger-like protrusions to achieve the snap fit as a simple design alternative."

222. For understandable reasons, Mr Acland for ResMed thought this should be explored and at the end of the first day of the trial (no doubt for the sensible purpose of being able to consider the answers overnight) he asked Mr Shi-Nash what alterations to Lovell he had in mind.

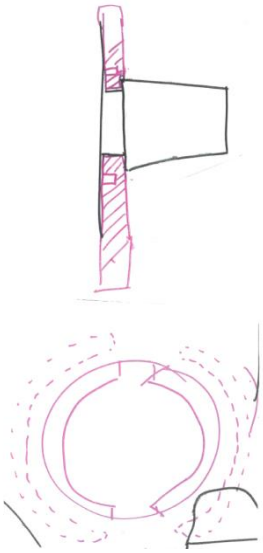
223. Mr Shi-Nash then did a series of drawings, and said that they were designs that he had thought of after his written report and not long before his oral evidence, because he expected that he would be asked what Mr Acland had indeed asked.

224. The drawings were as follows:

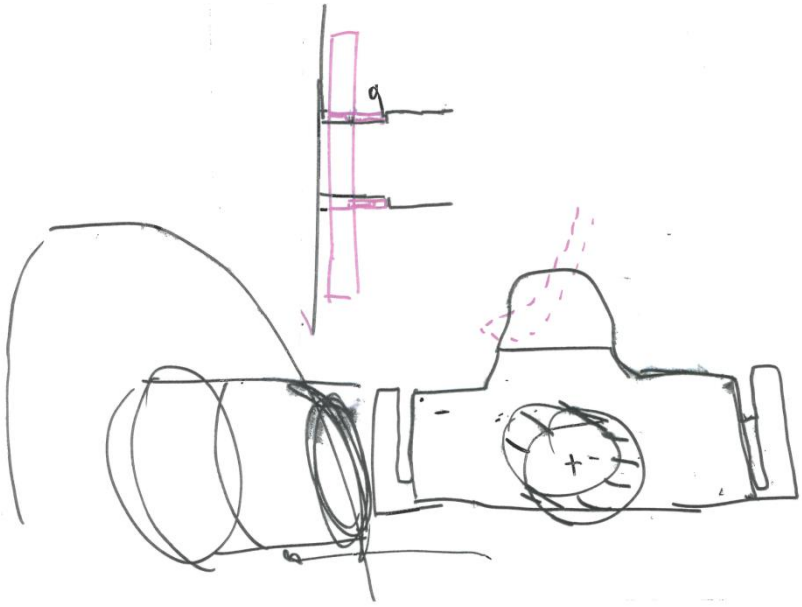
First proposal:



Second proposal:



Third proposal:



225. In the first proposal the two near-semi-circular protrusions are separated into more numerous, smaller individual protrusions by leaving more gaps. Mr Shi-Nash said this would add flexibility if desired. It would move Lovell closer to the 258 patent either if it were a requirement that the finger flex appreciably, or if it were necessary to make the protrusions individually more finger shaped.

226. In the second proposal, undercuts are added to each protrusion, again to make them more flexible. This again would help if the claims of the 258 patent required that the finger flex appreciably.

227. In the third proposal, which is more radical, fingers are used in a different orientation, on the retainer, pointing axially toward the front (to the right in the drawing above). They fit into a longer depression on the collar.

228. As to the first two proposals, Mr Plascott gave some ground but maintained the position that even with them the protrusions would not flex appreciably because they would be too stubby. The second proposal was mainly put to him in conjunction with the first (i.e. multiple protrusions each having an undercut).

229. I find that the first two proposals would be obvious workshop modifications on the balance of the expert evidence and having regard to the fact that multiple circumferentially spaced protrusions and fingers thinned along their profile for flexibility are both shown in Malloy. I find that separately or in combination they could achieve the objective of having the fingers flex. They do not make much difference to my analysis, because they would only be implemented if the skilled team had already decided that they wanted the protrusions to flex (as I have decided would be an obvious option), and the team could do that by choosing appropriate materials, especially given that only a small absolute size of deformation would be needed.

230. They nevertheless provide some further support for FPH's overall position in relation to flexibility and I agree that if the claim requires some sort of more finger-like shape then the first modification would satisfy that requirement in that it leads to stubby trapezoids akin to the preferred embodiments of the 258 patent.

231. I was considerably more troubled by the third proposal.

232. As Mr Plascott pointed out, by comparison with Lovell it involves using longer, thinner protrusions sticking out where they could be damaged, and it is more complex.

233. In the cross-examination of Mr Shi-Nash, Mr Acland put to him that the third proposal involves the deflection of the finger being at a maximum at the start of fitting the collar, declining as the collar moves closer to engagement, and Mr Shi-Nash suggested modifications to his design in response. Although this dialogue emphasised that the proposal was not fully thought out, I did not think that it revealed any fundamental flaw in it. Mr Shi-Nash did not accept that there was a serious problem.

234. I must also take into account the unsatisfactory way in which the proposals entered the case, as explained above, and which resulted in them being incompletely thought out and having been devised when Mr Shi-Nash knew the target of claim 1. This all counts against FPH, but as Mr Purvis pointed out the proposals are in the case now, and Mr Acland did have a fair opportunity to prepare to cross-examine on them, in the context of this simple mechanical case.

235. Despite these significant points and not without some hesitation I conclude that the third proposal is also obvious. Ultimately it just involves conventional snap fingers

protruding in the direction of engagement of the two components, which is shown in a number of figures of Malloy. Indeed figure 6.13 of Malloy shows multiple circumferentially spaced cantilever beams together forming a slotted annular snap assembly, which is very similar to the third proposal (although the mating component is outside the slotted component in Malloy, while it is inside in the third proposal). So I do not think the complexity or the fact that fingers protrude (and so could be damaged) is out of the ordinary.

236. So I think this is really just a workshop modification using another, slightly different tool in the skilled team's armoury to make the snap-fit connection. I do not think motivation is particularly relevant in this context, but I think the skilled team might move to the third proposal if the protrusions inside the circumference of the hole in the retainer were not deflecting enough, or just because it would be more familiar to them (from the kind of thing in Malloy figure 6.13) than the specific arrangement in Lovell. These are modest rather than overwhelming motivating factors to be sure, but sometimes that is enough for obviousness, and so I find here.

237. This conclusion means that Lovell renders claim 1 of the 258 patent obvious even on the narrowest claim scope argued for by ResMed.

238. As to claim 2, the argument here is very similar to that over Geist and I find it obvious for the same reasons, mutatis mutandis. The point about directing air flow does not run (because in Lovell the vent is in the elbow) so ResMed's case is weaker if anything.

239. Claim 9 is obvious for exactly the same reasons as apply to Geist. ResMed did not argue that there was any difference between the two citations relevant to this point.

240. Claim 12 requires one or more protrusions. I have found in connection with anticipation that this feature is present by virtue of the shoulder on the collar where it changes thickness. No additional point arises in the context of obviousness.

241. Claim 14 requires co-moulding. I find it obvious for the same reasons as applied with Geist. ResMed has the additional point that Lovell provides a specific cushion having a bladder filled with silicone gel, and that that would be, or would seem to be, complex and difficult to accommodate with co-moulding. That is beside the point, however: the skilled person would see the gel filled bladder as an optional extra. It would be

uninventive to use a conventional cushion and the common general knowledge was that that could be co-moulded.

INFRINGEMENT

242. ResMed contended that the Simplus and Eson masks each infringe claims 1, 9, 12 and 14 of the 258 patent, and that the Simplus mask additionally infringes claim 2.

243. FPH accepted that on its arguments as to claim scope there was infringement of all the claims except claim 2, which raised the additional point about the "top end" of the shroud given that the Simplus mask has a forehead support. On my finding as to claim scope the Simplus mask would infringe claim 2 if valid because the top of the forehead support is not the same as the top end of the shroud.

244. So all the claims relied on would have been infringed if they were valid.

CONCLUSION

245. The 258 patent is invalid for anticipation and obviousness over Geist and over Lovell. Had it been valid it would have been infringed.