Australian Government
IP Australia

5 July 2024

Patents Trade Marks Designs Plant Breeder's Rights

Delivering a world leading IP system

Phone: 1300 651 010
International: +61 2 6283 2999

www.ipaustralia.gov.au

ABN: 38 113 072 755

Opposition - Decision Issued

King & Wood Mallesons
Level 27
Collins Arch
447 Collins Street
Melbourne VIC 3000
Australia

Application number	2020223628, 2021201838, 2021201840, 2021201841, 2021201842 and 2021201843
Applicant name	Fisher & Paykel Healthcare Limited
Opponent	ResMed Pty Ltd

Dear Sir/Madam,

Please find attached a copy of a Decision of a Delegate of the Commissioner of Patents.

This decision may be appealed to the Federal Court. You can obtain more information from the website – www.fedcourt.gov.au.

Yours sincerely,

Linda Tobes
Oppositions and Hearings
Phone: +61 2 6283 2455

IP AUSTRALIA

AUSTRALIAN PATENT OFFICE

***ResMed Pty Ltd v Fisher & Paykel Healthcare Limited* [2024] APO 30**

Patent Application:	2020223628, 2021201838, 2021201840, 2021201841, 2021201842 and 2021201843.
Title:	Patient Interface and Aspects Thereof
Patent Applicant:	Fisher & Paykel Healthcare Limited
Opponent:	ResMed Pty Ltd
Delegate:	L. F. McCaffery
Decision Date:	5 July 2024
Hearing Date:	27 and 28 March 2024 in Melbourne
Catchwords:	**PATENTS** – opposition under section 59 to grant of patents – novelty – priority date of claims – claims entitled to earliest priority claimed – consideration of request that regard be had to information filed pursuant to regulation 5.23 – information would not change the outcome of the opposition in a significant way and not taken into account – inventive step – support – clarity – succinctness – utility – manner of manufacture – opposition unsuccessful on the grounds pressed by the opponent at the hearing – additional consideration of support pursuant to section 60(3) – claims of 2021201841 lack support – applicant given the opportunity to amend – pending an appeal, 2020223628, 2021201838, 2021201840, 2021201842 and 2021201843 directed to proceed to grant – parties given two weeks to make written submissions on costs.
Representation:	Counsel for the applicant: Tom Cordiner KC and Megan Evetts Patent attorney for the applicant: Matthew Swinn, Ann-Kathrin Goller and Vicky Zhang from King & Wood Mallesons Counsel for the opponent: Craig Smith SC Patent attorney for the opponent: Robynne Sanders, Ben Mawby and Nicole Harrowfield from DLA Piper

IP AUSTRALIA

AUSTRALIAN PATENT OFFICE

Patent Application:	2020223628, 2021201838, 2021201840, 2021201841, 2021201842 and 2021201843.
Title:	Patient Interface and Aspects Thereof
Patent Applicant:	Fisher & Paykel Healthcare Limited
Date of Decision:	5 July 2024

DECISION

The oppositions (on all applications) are unsuccessful on the grounds pressed by the opponent at the hearing.

While it was not raised by the opponent in their opposition, the claims of 2021201841 are not supported as they do not include the feature of the face-contacting side of the seal being supple to conform under internal pressure to the surfaces of the nose of the wearer, including at the side portions of the seal, to outside surfaces of the sides of the nose.

The applicant has two (2) months from the date of this decision to propose amendments to 2021201841 to overcome the issue.

Subject to appeal, I direct that 2020223628, 2021201838, 2021201840, 2021201842 and 2021201843 proceed to grant.

Parties given two (2) weeks to provide written submissions on the award of costs.

REASONS FOR DECISION

Background

1. Australian application 2020223628 (**'628**) was filed on 24 August 2020 by Fisher & Paykel Healthcare Limited (**the applicant**).

2. Applications 2021201838 (**'838**), 2021201840 (**'840**), 2021201841 (**'841**), 2021201842 (**'842**) and 2021201843 (**'843**) were all filed on 24 March 2021. These are divisional applications of '628.

3. The present applications are all members of a family of related patents and applications that include a number of granted patents and lapsed applications, as well as another two applications that are the subject of separate opposition proceedings.

4. The opposed applications were all advertised as accepted on 22 July 2021. Notices of opposition were filed by ResMed Pty Ltd (**the opponent**) on 21 October 2021. The same evidence was filed for all of the oppositions:

	Date of Declaration	**Annexes**
Evidence in support		
Melody Crinion	21 April 2022	MC-1 to MC-9
David John Palkon (**Palkon 1**)	21 April 2022	DJP-1 to DJP-64
Gregory James	21 April 2022	GJ-1 to GJ-6
Robynne Lyndsay Sanders (**Sanders 1**)	21 April 2022	RLS-1 to RLS-124
Evidence in answer		
Jason Eaton	11 August 2022	JE-1 and JE-2
Evidence in Reply		
David John Palkon (**Palkon 2**)	16 October 2022	DJP-1 (65)
Robynne Lyndsay Sanders (**Sanders 2**)	17 October 2022	RLS-125 to RLS-164

Regulation 5.23 material

5. Following completion of evidence in reply, the applicant submitted that Sanders 2, with the exception of paragraph 11 and Annexes RLS-131 and RLS-132, and Palkon 2, paragraphs 264 and 265 were not properly evidence in reply. Following comments from the parties, a delegate made the direction:

> *"That paragraphs 5-25 and 28-34 of the Sanders #2 declaration (filed 17 October 2022) and annexures RLS-126 to RLS-155 and RLS-158 to RLS-164 (filed 17 October 2022) are not properly in reply and are not admitted into evidence."*

6. Pursuant to this direction, the applicant sought to file evidence under Regulation 5.23 (Eaton 2). The evidence was intended to deal with paragraphs 264 and 265 and Annex DJP-1 of Palkon 2. However, this led to several further rounds of evidence and submissions as the parties disputed whether certain material was limited to evidence in reply and whether even more evidence should be allowed under regulation 5.23. The parties agreed to a direction proposed by the delegate, and made on 16 January 2023, that Eaton 2 be consulted in the opposition. The opponent was given 1 month to file evidence or submissions in reply, and filed Sanders 3, Abhyankar and Palkon 3 on 28 February 2023.

7. The applicant considered that the opponent's response was not properly in reply, and in a letter of 10 March 2023, contrary to the usual approach of seeking to have the evidence struck out

and without any indication of why they considered the evidence was not properly in reply, advised that they intended to file further evidence under regulation 5.23. The applicant subsequently filed Eaton 3 together with a request to have this evidence consulted under regulation 5.23, or in the alternative, to have the opponent's evidence (with the exception of Palkon 3, paragraphs 1 to 7 and 13 to 15) excluded on the basis that it was not in response to Eaton 2.

8. Following a detailed consideration, the delegate agreed with the applicant's submissions and proposed a direction that, with the exception of paragraphs 1 to 7 and 13 to 15 of Palkon 3, the evidence filed by the opponent on 28 February 2023 be disregarded in the opposition. This led to further correspondence between the opponent and the delegate before, in a letter dated 10 May 2023, the delegate proposed that the issue be left for consideration at the hearing. I have dealt with this issue in my discussion of the Respironics ComfortCurve™ mask under novelty.

9. A summary of the evidence filed following the completion of EIR is given in the following table.

	Date of declaration	**Annexes**
Evidence allowed under Reg. 5.23		
Jason Eaton (**Eaton 2**)	9 January 2023	
Evidence in reply to Eaton 2 requested under Reg. 5.23 (not yet allowed)		
Robynne Lyndsay Sanders (**Sanders 3**)	28 February 2023	
Sonali Abhyankar (**Abhyankar**)	27 February 2023	SA-1 to SA-3
David John Palkon (**Palkon 3**)	27 February 2023	
Evidence requested under Reg. 5.23 (not yet allowed)		
Jason Eaton (**Eaton 3**)	30 March 2023	

10. The matter was set for hearing on 27 and 28 March 2024. The opponent pressed the grounds of novelty, inventive step, clarity, support, succinctness, utility and manner of manufacture at the hearing.

11. Following the hearing, on 3 June 2021 I wrote to the parties seeking submissions on matter of concern I had concerning section 40(3) in relation to application '841, where these concerns had not been raised by the opponent. The parties provided their responses on the issue on 18 June 2024. This is further discussed under the ground of support below.

Onus

12. The substantive amendments to the *Patents Act 1990* (Cth) (the ***Act***) brought about by the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth) (**the *RTB Act***) apply to the present case. The standard of proof in opposition proceedings is the balance of probabilities. If the Commissioner is satisfied, on the balance of probabilities, that a ground of opposition to the grant of the standard patent exists, the Commissioner may refuse the application. The opponent bears the onus of proof.

The expert witnesses

13. As indicated above, the opponent relied on evidence from the following witnesses:

- Melody Crinion is a Senior Paralegal employed by ResMed. Her evidence relates to documents and devices that are maintained by ResMed and entered into evidence in the opposition.
- Gregory James is Vice President of Corporate Finance and Treasury at ResMed. His evidence related to records of sales that were provided as evidence of public availability of prior art products in evidence.
- David John Palkon is the owner and Director of an engineering consultancy business, IBT Consultants. He was the main technical expert for the opponent. Between 1997 and 2006 he provided consultancy services to Tiara Medical Systems, Inc., a medical device manufacturer. This included projects on the design and commercial development of several nasal and full face masks. He is listed as an inventor on 8 patents.
- Robynne Lyndsay Sanders is a Partner of DLA Piper Australia. Her evidence included various comparisons of claims and priority documents, as well as entering a large number of documents into evidence.
- Sonali Abhyankar is a Clinical Development Specialist at ResMed, where, as a Sleep Technician, she works with patients who are undertaking sleep studies or have been diagnosed with sleep apnea, fitting them with masks. Her evidence related to the fitting of a ComfortCurve™ mask.

14. The applicant relied on evidence from Jason Eaton, who is currently a Principle Mechanical Engineer in New Product Development at MSA Safety Incorporated. Between 2000 and 2012, he was employed by Respironics, Inc., which became Philips Respironics in 2008. During that time, he was lead engineer for the design and commercial release of the ComfortGel™ nasal mask.[1] He was also on the team involved in early concept development brainstorming sessions for the ComfortCurve™ product,[2] as well as leading projects related to infant sleep apnea and phototherapy devices.[3] He is named as an inventor on 25 patents.

15. The parties did not dispute that Mr Palkon and Mr Eaton have appropriate knowledge and experience to provide evidence on the present matter. However, the applicant submitted at the hearing that Mr Palkon took an over-meticulous approach to his construction of the specifications. They also noted that Mr Palkon's own patent specifications used language that he stated was unclear in meaning in the present cases. On the other hand, the opponent submitted that Mr Eaton misunderstood the role of the body in construing patent claims, and that his approach was flawed as he read the specification and drawings as if they provide a dictionary for the meaning of certain terms in the claims.

16. I have taken these matters into account when assessing the weight that evidence may be given in my determination.

The common general knowledge

[1] Eaton 1 at [9].
[2] Eaton 1 at [24].
[3] Eaton 1 at [30] to [36].

17. A significant cause of sleep breathing disorders is the collapse of loose tissue in a patient's airway during sleep. This can cause the airway to become obstructed and the patient to stop breathing. Continuous Positive Airway Pressure (CPAP) therapy is used to maintain positive air pressure in the patient's airway to support the loose tissue and allow the patient to breathe more freely.[4]

18. CPAP therapy uses a flow generator to create pressurised air which is delivered via a tube to a mask secured to the patient's face by headgear. There were three main types of mask:

    a. Full-face masks, which typically sealed around the mouth and at least some portion of the nose and cheeks;

    b. Full nasal masks, which typically sealed around most of the nose exterior and above the upper lip, and often portions of the cheeks; and

    c. Nasal pillows masks, which typically sealed around the nostrils.[5]

19. Mr Eaton identified another type of CPAP mask, cannula-style masks, which typically do not have a mask frame and have prongs which insert into the user's nostrils. The Innomed Nasal Aire II Prong Mask™ is an example of such masks.[6] Mr Palkon appears to have included such nasal cannula masks in his reference to nasal pillows,[7] but also stated that, while he was aware of masks like the Innomed product, he did not consider it a true alternative to the types of masks identified above because patients found it to have very poor comfort and effectiveness, and compliance was low because it caused sores inside some patient's noses.[8] Mr Eaton went on to state that the different types of interface existed more on a spectrum than in clearly defined and separate categories. For example, the difference between nasal pillows and cannula-style masks can be as little as the degree of extension of the seal into the nares (nostrils).[9]

20. Certain features were generally common to all masks at the priority date:

    - A rigid plastic frame;[10]
    - Soft cushions for areas that contacted the user's face, so as to achieve a seal against the user's face;
    - Headgear that held the mask to the user's face; and
    - Some kind of swivelling attachment that connected the tube to the mask, and at the other end to the flow generator, that delivered the pressurised air.[11]

21. The frame provides a relatively rigid attachment point for the tube and the headgear which hold the mask against the user's face,[12] and may be made of polycarbonate, silicone and polyethylene.[13] Mask frames are generally designed to be low profile, but because they needed to fit faces of different shapes and sizes, as well as avoid contact with the user's face, they

---

[4] Palkon 1 at [90] to [91].
[5] Palkon 1 at [93] and Eaton 1 at [76].
[6] Eaton 1 at [77].
[7] Palkon 1 at [51].
[8] Palkon 2 at [39].
[9] Eaton 1 at [79].
[10] Cannula-style masks often do not have a frame. See Eaton 1 at [100].
[11] Palkon 1 at [95].
[12] Palkon 1 at [104].
[13] Palkon 1 at [108].

cannot be too low profile.[14] To avoid discomfort, the internal volume of the frame also has to provide sufficient volume for an inflatable seal to inflate and for the pressurised air to circulate before entering the user's nose or mouth.[15]

22. Tubes from the air flow generator were either connected directly to the mask or connected through an elbow. The tube/elbow was usually connected to the frame of the mask as this part of the mask was stiffer and better able to absorb the forces applied by the tube/elbow. Most elbows contained a swivel that allowed the tube to rotate independently of the mask.[16]

23. Full-face and full nasal masks were generally in the shape of a triangle with rounded corners. Mr Palkon stated that nasal pillows were generally shaped like a U to a V,[17] but Mr Eaton considered this an "arbitrary" description and that it was not correct to say that *all* nasal pillows had this shape. Nevertheless, he recalled that it was common for the geometry of nasal pillows to match the typical contours of the nose and to extend laterally outwards, and sometimes slightly backward towards the user's face,[18] which I understand to essentially describe a shallow V- or U-shape.

24. The cushion generally creates the seal against the user's face, and the evidence therefore used these terms interchangeably. Cushions can be permanently attached to the frame by adhesives or by overmoulding and aftermoulding during manufacturing, or removably attached using methods such as retaining rings and clipping mechanisms.[19] Cushions generally form the seal in one of two ways. The seal may be pressed into the user's face until it conforms to the contours of the face. Gel and liquid silicone seals work in this way. Alternatively, the cushion is placed in partial contact with the user's face and pressure within the mask used to inflate the seal until it conforms to the user's face. This is how some silicone cushions function.[20]

25. The cushion that contacts the user's face must be soft. Silicone with a higher hardness rating than other silicone options allows a thinner layer to be used to achieve the desired properties, but hard silicone in areas that contact the user's face can cause discomfort. While a thin layer of silicone is ideal, very thin layers of silicone do not hold their shape and are difficult to remove from moulds. Mr Palkon stated that he was unaware of any mask cushion that was more than 6.35 mm thick, as above this thickness the cushion would be too rigid, heavy and expensive.[21]

26. If certain parts of the mask require additional rigidity, reinforcing features such as strips or ribs may be incorporated. The thickness of the silicone may also be varied, making it thicker where the mask needs to be stiffer and thinner where it needs to be more flexible, or where it contacts the face. For example, many masks use thinner silicone on the bridge of the nose because this area is quite sensitive. Thicker silicone is used in the area between the lips and cheeks which was less sensitive, but also more prone to leakage. Thicker silicone gave the cushion greater stiffness and improved the seal.[22]

---

[14] Eaton 1 at [99].
[15] Palkon 1 at [110] and Eaton at [99].
[16] Palkon 1 at [98] to [100].
[17] Palkon 1 at [114].
[18] Eaton 1 at [79].
[19] Palkon 1 at [126].
[20] Palkon 1 at [116].
[21] Palkon 1 at [119] to [122].
[22] Palkon 1 at [123] to [124].

27. The purpose of the headgear is to securely hold the mask against the user's face whilst maintaining correct orientation and equal pressure across the face, without bending or pushing too hard against the face. Keeping the mask in place is critical to achieving the best seal. Headgear is generally made of fabric that wraps around the back of the head and is adjustable to differently sized heads, for example by using Velcro at the ends of the straps.[23]

28. Headgear is generally attached to the frame via slots or clipping mechanisms that are positioned to avoid the eyes and ears. It is possible to attach the headgear to the cushion, but this is problematic as the cushions are not designed to withstand the force of being pulled by the headgear, and it can cause the cushion to deform.[24]

29. Masks generally incorporate stability or support features to ensure the seal remains effective despite forces from the pressurised air and movement of the user during sleep.[25] The bridge of the nose (the upper bony part of the nose) is a particularly sensitive area as it has a very thin layer of skin, and any amount of pressure in this area is likely to cause discomfort. However, if the mask is not properly sealed around the bridge of the nose, air leakage can be directed into the user's eyes.[26] It is therefore common to include a forehead support which allow the mask to be pushed closer to or pulled away from the user's face using the headgear tightness. This allows the user to customise the position of the mask and the pressure that is being applied to the bridge of their nose.[27]

30. Mr Eaton stated that it was also an option to use cheek supports instead of, or in addition to, forehead supports. The Respironics ComfortCurve™ included cheek supports to provide stability to a relatively small mask through features other than the seal surface itself. He went on to state that it was common to want to decouple the sealing and stability functions of the mask and provide stability primarily through features other than the seal (such as the cheek or forehead supports). However, the seal itself could include support features and contribute to overall stability.[28] For the ComfortGel™ nasal mask, the sealing and support functions provided within the seal were decoupled though use of a gel cushion, which helped stabilise the mask on the user's face, immediately interfaced with a thin and compliant silicone flap which contacted and sealed to the user's face. This apparently was an uncommon approach to mask design, so I do not consider that it can be taken to be common general knowledge.[29]

The specifications and claims

31. Turning to the present applications, I note that the text of the specifications differs only in the Summary of the Invention sections. This results in some differences in the pagination of each application, but for convenience I will refer to the page numbers used in '628 unless otherwise indicated.

32. The field of the invention relates to patient interfaces for delivering breathing gases to a patient and aspects of patient interfaces. The invention is said to be described with reference to patient

[23] Palkon 1 at [137] to [139]
[24] Palkon 1 at [145] to [146].
[25] Eaton 1 at [90].
[26] Palkon 1 at [113].
[27] Palkon 1 at [111] to [113], Eaton 1 at [90] to [92].
[28] Eaton 1 at [95].
[29] Eaton 1 at [96].

interfaces for delivering PAP therapy to a patient, for example, to a patient suffering obstructive sleep apnea (OSA) but could be used for other treatments.[30]

33. The Summary of the Invention then sets out a number of consistory clauses and various aspects of the invention, which also appear in the claims. The first aspect of the invention is said to:

> "consist in an inflatable nasal seal for a patient interface: the seal including a face contacting side, the seal being formed of a soft flexible material, and including a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each side portion extending across a side of the nose, the face contacting side of the seal being supple to conform under internal pressure to the surfaces of the nose of a wearer, including, at the side portions of the seal, to outside surfaces of the sides of the nose, an exterior side of the seal including regions much stiffer than the supple interior side, the regions extending into the side portions of the seal."[31]

34. The specification goes on to say that:

> "According to a further aspect, the seal includes a pair of nasal locators on the face contacting side, and the seal is stiffer in the region immediately adjacent and including the nasal locators than in a region surrounding this region, on the face contacting side of the seal."[32]

35. The above passages suggest that "nasal locators" are an optional feature of the invention. However, all of the embodiments in the Detailed Description comprise nasal locators. This was a point of some contention between the parties, and in particular the weight that the consistory clauses could be given. This issue is further discussed under the ground of support.

36. The seal is said to be formed from a supple material that is capable of repeated deformations without failure. Suitable materials include latex, vinyl, silicone and polyurethane. The wall thickness is below 0.5 mm and can be lower than 0.2 mm.[33]

37. The seal is supported by a mask body or frame. The inlet opening of the seal is fitted to the frame, or directly to a conduit extending through the frame. The frame may be formed by injection moulding of an elastomeric material such as silicone or polyurethane, but rigid materials such as polycarbonate, polyester, polystyrene or nylon may alternatively be used. The preferred frame includes connection points for connecting straps to the frame. The nasal seal body may also include integral strap attachment points. These may be connection elements on the surface of the envelope, but alternatively can be integral straps or wings formed in the envelope that extend out from either side of the envelope.[34]

38. The specification sets out numerous embodiments relating to different aspects of the patient interface, including 62 figures. For brevity I have not gone into detail about these here, but some are discussed in relation to other issues below.

---

[30] Specification at page 1, lines 7 to 9.
[31] Specification at page 1, line 23 to 30.
[32] Specification at page 4, lines 20 to 22.
[33] Specification at page 14, line 10 to 14.
[34] Specification at page 14, line 27 to page 15, line 3.

39. The claims of each the applications[35] have the following features in common:

- An (inflatable[36]) nasal seal;
- The (nasal) seal including a face contacting side, the seal being formed of a soft flexible material; and,
- Including a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each[37] side portion extending across a side of the nose.

40. Most of the opposed applications[38] also define the feature:

- The face contacting side of the seal being supple to conform under internal pressure to the surfaces of the nose of a wearer, including, at the side portions of the seal, to outside surfaces of the sides of the nose.

41. Claim 1 of each application includes additional characterising features, which I have summarised below. Before considering those features, I will construe the meaning of some of the terms that are common between most of the applications. In this regard, the opponent submitted that there is a remarkable lack of detail in Claim 1 – no overall shape for the nasal seal is defined and there is no description of the shape of any of the parts of the nasal seal.[39] Claim 1 includes few design limitations that would assist the skilled person to go about designing a mask. This concern appears to stem from the use of relatively imprecise terminology, which the opponent refers to as "undefined" terms and the terminology used to characterise these.[40] Some of these issues were raised under section 40 grounds and are discussed in detail later in the decision.

Construction

42. The principles underpinning construction are well-established. As noted by Middleton J in *Eli Lilly and Company Limited v Apotex Pty Ltd*:

> "It is well settled that the Court should, from the outset, approach the task of patent construction with a generous measure of common sense. The Court must place itself in the position of a person skilled in the relevant art, being the subject matter of the patent. From this perspective, the patent is to be read as a whole, in the context of the specification and in light of the prevailing common general knowledge and state of the relevant art at the priority date."[41]

43. Thus, the task of construing the specification is undertaken from the viewpoint of a person skilled in the art and the prevailing common general knowledge at the priority date. The person skilled in the art is a hypothetical, non-inventive person or team likely to have a practical interest in the subject matter of the invention.[42]

---

[35] The claims of each application are set out in the Annexes in full.
[36] Claim 1 of only '628 and '841 explicitly define that the nasal seal is inflatable.
[37] '838 defines "*the* side portions extending across a side of the nose" rather than "*each* side portion extending across a side of the nose". This does not appear to be significantly different in meaning.
[38] The claims of '841 do not define this feature. This is discussed in more detail under the ground of support.
[39] Opponent's written submissions for the hearing (**OS**) at [30].
[40] OS at [58].
[41] [2013] FCA 214; 100 IPR 451 at [139].
[42] *Root Quality Pty Ltd v Root Control Technologies Pty Ltd* [2000] FCA 980 at [70]-[72].

44. The Full Court in *Airco Fasteners Pty Ltd v Illinois Tool Works Inc*. recently reiterated the principle that experts can give evidence on the meaning which those skilled in the art would give to technical or scientific terms and phrases, and on any unusual or special meanings that would be given by skilled addressees to words which might otherwise bear their ordinary meaning. The Court is to place itself in the position of some person acquainted with the surrounding circumstances as to the state of the art and manufacture at the time. However, it is for the Court, not for any witness however expert, to construe the specification.[43] A similar approach is taken in matters before the Commissioner.

45. As also noted by Justice Rofe in *Sandoz AG v Bayer Intellectual Property GmbH,* a construction that would lead to an absurd result is to be avoided. It is impermissible to approach the issues of construction with any regard to the alleged infringing articles,[44] better understood for present purposes as the prior art.

Inflatable nasal seal

46. There was no apparent dispute between the parties that an "inflatable nasal seal" is a pressure assisted seal or cushion that forms a seal when the pressure within the mask inflates the seal until it deforms outwards and conforms to the user's face to seal the user's nose.[45]

47. I note that claim 1 of only applications '628 and '841 explicitly defines an inflatable nasal seal. In contrast, claim 1 of applications '838, '840, '842 and '843 define nasal seals without any reference to them being inflatable. Both experts considered the omission of the term "inflatable" meant that the nasal seals could be a non-inflatable seal, such as masks with physical seals.[46] But claim 1 goes on to define that the seal is supple to conform under internal pressure to the outside surfaces of the sides of the nose, so I consider this imparts a limitation on the claim that the seal is at least pressure-assisted inasmuch as the internal pressure pushes the seal (or at least some part of it) against the surfaces of the nose.

48. However, claim 2 of '838, '840, '842 and '843 define that the seal is inflatable. Construing the claims to avoid redundancy in claim 2 might suggest that claim 1 includes pressure-assisted seal types other than inflatable seals (for example Mr Eaton referred to one type of pressure-assisted seal as a flap seal[47]). Despite this concern, there is no evidence of there being a distinction between inflatable seals and any other type of pressure-assisted seals. While this may result in Claim 2 of applications '838, '840, '842 and '843 being redundant, this in itself is not a determinative factor in the construction of the claims.[48]

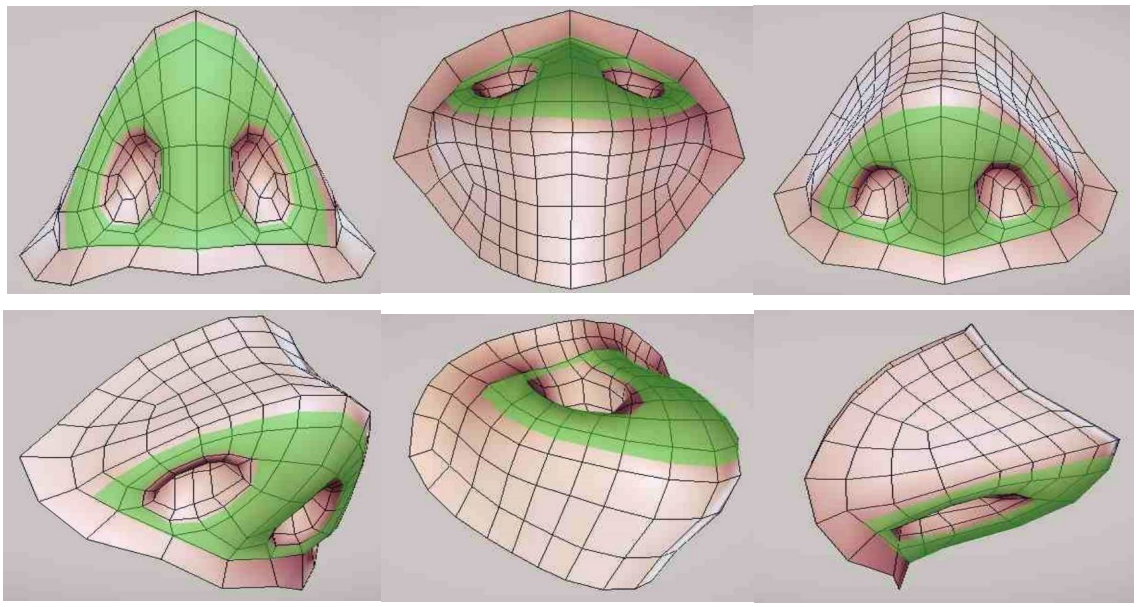
Across the base of the nose

49. There was some dispute between the experts as to what the base of the nose encompasses. Despite stating that he would generally refer to the base of the nose as the entire triangular section,[49] Mr Palkon went on to say that the phrase "base of the nose" was not clear to him as to whether it refers to the part of the nose that meets the lip and extends from one nostril to the other (shown in red below), or whether it comprises the entire bottom triangular section of the

[43] [2023] FCAFC 7 at [48].
[44] [2023] FCA 1321 at [151] to [152].
[45] Palkon 1 at [183], Eaton 1 at [134] to [135].
[46] Palkon 1 at [354], Eaton 1 at [222].
[47] Eaton 1 at [11], [16], [88] and [96].
[48] *Sandoz AG v Bayer Intellectual Property GmbH* [2023] FCA 1321 at [153].
[49] Palkon 1 at [209].

nose (shown in green below). The specification did not assist him to understand the meaning of the term.[50]

50. Mr Eaton stated that the base of the nose would refer to the surface of the nose visible from a viewpoint below the user's nose, looking upwards. Mr Eaton also referred to the relevant area as the alar base,[51] but the specification does not describe the invention in such anatomical terms. He provided diagrams from several different angles to further explain:



51. On balance, I am satisfied that the base of the nose can be taken to be the area indicated in green in the diagrams above. The experts appear to be in agreement that this would be the ordinary meaning of the term. While Mr Palkon went on to provide the alternatives above, ostensibly because the specification did not provide a definition, he provided no explanation of why he would defer from the ordinary meaning. The fact that the specification does not provide an alternative definition leads me to conclude that the ordinary meaning of the term would be taken.

52. It is probably unnecessary to consider the issue any further, but I also note that the central portion is defined to extend *across* the base of the nose. I understand the plain meaning of the term "across" to indicate that the central portion extends in two dimensions – length and width – as opposed to, say, the central portion being positioned *along* the base of the nose which

[50] Palkon 1 at [210].
[51] Eaton 1 at [150].

indicates a single dimension (the length). The term "across", as used in the claims, is consistent with the former interpretation and the meaning I have accepted above.

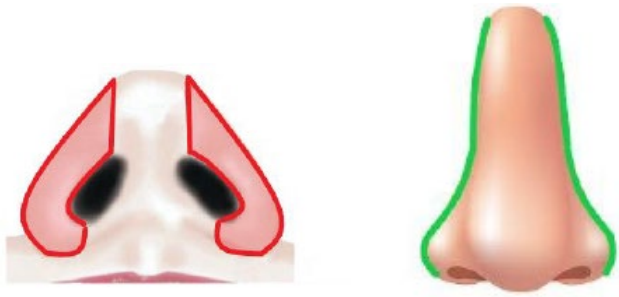
Side of the nose, face-contacting side, exterior side

53. The experts differed as to the meaning of several terms that perhaps highlight the different meanings words can take depending on the context in which they are used. In particular, the term "side" is used in different ways in the claims:

- The seal has face-contacting and exterior sides.
- Each side portion of the seal extends across a side of the nose, and the seal conforms under internal pressure to the outside surfaces of the sides of the nose.

54. On the first issue, Mr Palkon stated that it was unclear to him how the seal could have a side when it is curved. The applicant disagreed, referencing Pink Floyd's "Dark Side of the Moon" to illustrate how a curved shape can have sides, in this case a light side and a dark side. I agree with the applicant on this point. In the present case, the two sides refer to the inward-facing surfaces of the mask and the exterior-facing surfaces of the mask. The boundary between these surfaces (or sides) is defined by the line at which the seal forms with the user's face.

55. On the second issue, Mr Palkon stated that it was not clear to him whether the term "sides of the nose" referred to the sides of the nostrils (shown in red below) or the outside edges of the nose, shown in green below.[52] Besides providing these two alternatives, Mr Palkon did not explicitly state what he would ordinarily understand the sides of the nose to be. In the first figure, he appears to refer only to the area on the base of the nose adjacent the nostrils (rather than the sidewall of the nose extending from the base to the bridge of the nose). In the second diagram, Mr Palkon appears to be referring only to the line between the nose and the cheek. The diagram does not appear to encompass the surface of the nose between the nasal ridge (the centre line of the nose between the tip and the bridge of the nose) and the cheeks, including the alae (the "wings" on either side of the nose, singular form being ala). As Mr Palkon provided little additional explanation of the diagrams, I have some difficulties in drawing any conclusions from this particular evidence.



56. In contrast, Mr Eaton appeared to have no difficulty with the terminology, stating that:

> "I understand the sides of the nose to be the portions on either side of the nasal ridge, including the generally forward and laterally facing surfaces of the alae. I understand the nasal ridge to be the midline prominence of the nose which extends from the top of the nasal

[52] Palkon 1 at [222].

> bridge to the front of the nasal tip. I understand the nasal bridge to be the upper most, bony part of the nose between the eyes and just below them, and the nasal tip to be the most projected part of the nose which points away from the user's face. I therefore understand the sides of the nose to comprise all portions of the nose except the surfaces of the lower face of the nose (i.e., the alar base) and the central or forward-facing surfaces of the nasal ridge."[53]

57. On balance I prefer the evidence of Mr Eaton. Mr Palkon did not provide a clear indication of what the ordinary meaning in the art would be, and *prima facie* his two alternatives are formulated to read on the prior art masks. Notably neither appears to be consistent with the definition provided by Mr Eaton. But if there are any construction issues of the type suggested by Mr Palkon, I consider these can be resolved fairly easily.

58. Given the ordinary meaning of the term 'base of the nose" as discussed above, the first interpretation given by Mr Palkon (shown in red), would not, in my opinion, be a common sense one. Firstly, the term "nose" is not synonymous with the term "nostrils" (or nares). The specification consistently uses the terms nose and nostrils differently, and there is no reason to think that the drafter has not been consistent in such an approach in their reference to the sides of the nose in the claims. Secondly, the claim defines that the seal extends across the base of the nose and across the sides of the nose. The separate identification of base and side portions indicates two different orientations rather than a continuation or extension in the same plane. Finally, having determined that the base of the nose would ordinarily be taken to include the surfaces surrounding the nostrils, the separate definition of the seal extending to the area around the nostrils in the manner suggested by the opponent would be superfluous.

59. Turning to the second alternative provided by Mr Palkon, my understanding is that the ordinary meaning of the term "side" when referring to a 2-dimensional shape is the outside boundary of the shape, such as the side of a square. Mr Palkon appears to approach the meaning of the term "sides of the nose" in this way in his second alternative. Thus, if the nose is viewed from the front as a 2-dimensional triangular shape, the sides of the nose (shown in green by Mr Palkon) are the outside boundaries of that triangular shape. In a three-dimensional shape, however, the faces (or surfaces) of the shape are generally referred to as sides, which are separated by edges. Given that the nose is a three-dimensional, essentially pyramidal, shape, the term "side" would be understood in that context to relate to a surface of the nose rather than an edge.

60. It seems to me that both interpretations are feasible if looking at the term "sides of the nose" in isolation and stripped of all surrounding context. However, in the context of the definitions given in the claim, I consider that the latter interpretation is the correct one. The central portion extends *across* the base of the nose and the side portions extend from the ends of the central portion *across* the sides of the nose. As discussed previously, the term *across* infers length and width, and therefore this combination of features clearly defines a surface rather than a line. If that is in any doubt, the claim goes on to define that the seal conforms under internal pressure to the *surfaces* of the nose.

61. This interpretation is consistent with the meaning given by Mr Eaton. However, I note that in response to Mr Eaton's evidence, Mr Palkon stated that he did not consider that the sides of the nose (the nasal ridge, nasal bridge, nasal tip and alar base) could be distinguished from other parts of the nose in the manner suggested by Mr Eaton above, as the parts of the nose differ

[53] Eaton 1 at [165].

from patient to patient depending on their nasal geometry.[54] I find this evidence unconvincing since the nasal anatomy referred to by Mr Eaton appears to be widely used and understood in the art. Indeed, Mr Palkon used similar language in describing a mask which he was involved in designing,[55] and in a general description of nasal pillows masks.[56] The transitions between the sides and base of the nose are certainly not sharp lines. But a degree of imprecision is permissible in patent claims providing the skilled person would be able to give the terms meaning. Moreover, I do not understand the claims to define a "one size fits all" mask. Rather, like any of the masks referred to by the experts in their evidence, the most appropriate mask size would be selected to suit the user's facial geometry. I consider Mr Eaton's interpretation provides a workable standard in that regard.

62. In summary, I understand anything that is visible from the underside of the nose comprises the base of the nose, while anything above the base, excluding the forward-facing ridge of the nose, constitutes the side of the nose. I will apply that meaning in my determination.

Central portion and side portion

63. One of the key construction issues raised at the hearing involved the meanings of the terms "central portion" and "side portion". My understanding of the opponent's submissions is that the meaning of these terms cannot be determined because they are not terms in the art and the claims provide few design details. The opponent submitted that in choosing to use such "deliberately general terms" the meaning of those terms must principally come from the context provided by the claims, read within the broader context provided by each specification as a whole.[57] They went on to submit that because there was no dictionary in the specifications that explained the terms, the claims must be construed to determine their meaning.[58]

64. I don't disagree with the general principles set out in these submissions, but I do not consider it unusual that an invention is described using "general" terms, or that such terms (or indeed any term, technical or otherwise) must be construed. I would also add that the terms in a claim are generally given their plain or ordinary English meaning,[59] unless they have a special technical meaning in the art.[60] This is done from the point of view of the person skilled in the art and what they would understand the terms to mean. In that regard, the opponent's written submissions on the construction of the terms "central portion" and "side portions" make no reference to the evidence given by the experts beyond a couple of criticisms of Mr Eaton's evidence.[61] This is perhaps not surprising given Mr Palkon's difficulties in giving the terms any definitive meaning, and the opponent's submissions to the extent that Mr Eaton's opinions should be disregarded because of his reliance on the specification to interpret the terms in the claims.

65. The opponent's written submissions referred to the terms "central portion" and "side portions" as "undefined" terms. They went on to make submissions in relation to several terms as summarised below:

---

[54] Palkon 2 at [113].
[55] Palkon 1 at [53].
[56] Palkon 1 at [93].
[57] OS at [54] to [57].
[58] OS at [58].
[59] *Interlego AG v Toltoys Pty Ltd* (1973) 130 CLR 461 at 478.
[60] *Electric & Musical Industries Ltd v Lissen Ltd* (1939) 56 RPC 23 at 41.
[61] OS at [54] to [66].

- The word "central" describes the location of the relevant part, being towards the centre of the seal, but the claim does not otherwise specify to what degree that region must be centred.

- The central portion is defined to extend across the base of the nose, but no degree of extension is specified in the claims. The opponent however acknowledged that some guidance is given by the requirement that the central portion must extend across the base of the nose.

- Each side portion extends across the side of the nose, but the degree of extension is not specified. The opponent noted that the claim does not impart a requirement that the extend across the full side of the nose and argued that this similarly meant that the central portion need not extend across the full base of the nose.

- The side portion extends from each end of the central portion, but there is nothing in the claims or specification that makes clear where the central portion ends, including relative to the full width of the base of the user's nose.

- The claim requires that the product operates as a nasal seal, and therefore the seal must contact the user's face in such a way that a seal will form with the user's face such that pressurised air is delivered to the nostrils. However, the claim does not otherwise provide any information as to the shape or extent of the nasal seal as a whole or the side or central portions of that seal. Such features are only introduced in dependent claims.

66. I note these generally relate to purported issues in interpreting certain terms in the claim rather than providing any resolution of those issues. The opponent's submissions also, to a large extent, construe the meaning of terms in isolation from other features of the claims, which risks an over-meticulous verbal analysis of the claims. As cautioned by the Federal Court in *Nesbit Evans Group Australia Pty Ltd v Impro Ltd*, "[t]here is a danger in considering the integers of a claim individually and in isolation. This could yield a literal rather than a purposive construction".[62]

67. That aside, I consider the issues raised by the opponent can be resolved to give the terms in the claim meaning. The central and side portions are defined with reference to the base and sides of the nose. The central portion is positioned across the base of the nose. As suggested by the opponent, this, in isolation, does not require that the central portion extend across the entire base of the nose. However, the claim defines that the side portions extend from each end of the central portion, and those side portions extend across the sides of the nose. I understand the reference to the side portions extending across the sides of the nose implies that the side portions are at least proximate to the sides of the nose. But even if this is not the case, the claims go on to define that the seal conforms under internal pressure to the surfaces of the sides of the nose. That is, the side portions must be sufficiently close enough to the nose to enable the seal to contact and conform to the outside surfaces of the sides of the nose when the seal is inflated.

68. To the extent that the central portion may not extend the entire distance of the base of the nose, I note the principle "*a construction according to which the invention will work is to be preferred to one according to which it may not do so*".[63] The claim requires that the side portions extend from the ends of the central portion and across the sides of the nose. I do not consider that the language of the claim contemplates that the central portion does not extend the full distance of

[62] [1997] FCA 1092; (1997) 39 IPR 56 (*per* Lindgren J).
[63] *Nesbit Evans Group Australia Pty Ltd v Impro Ltd*, *supra*.

the base of the nose. This would seem to result in an absurd result, or at least one which would not work in the way required, since such an arrangement would presumably result in pinching or blocking of the nares.

69. I also do not share the concerns of the opponent in relation to the degree of extension of the side portions. I agree that the definition does not impose a requirement that the side portions extend the entire length of the nose, though this degree of extension does fall within the scope of the claim. The opponent acknowledged that the specification provides some contextual guidance for the lower end of extension, referencing the disclosure of the specification that the side portions should extend at least 10 mm,[64] but I don't understand the claims to be limited to this specific size. Rather, I construe the definition of the side portions as extending across the sides of the nose and expanding under internal pressure to conform with the surfaces of the nose of the wearer, including the outside surfaces of the nose, as meaning that it forms a seal with the outside surfaces of the side of the nose. This requires more than simply a *de minimis* degree of contact. The side portions do not merely touch the edges of the sides of the nose but extend across the surfaces of the sides of the nose and conform to them.

70. The opponent's concerns on these matters stems from the lack of detail, or imprecision, in the definitions used in the claims. However, a degree of imprecision is permissible in claims provided the person skilled in the art would be able to determine the meaning. Indeed, it seems to me, given the differences in facial geometry, that the person skilled in the art of nasal masks would expect there to be a degree of variability in the fit of any mask. The central portion may not align precisely with the base of all noses, but to all intents and purposes that is one of the aims of the seal inflating to conform with the outer surfaces of the sides of the nose. In summary, the claim does not set out precise measurements for the central and side portions, but I am satisfied that the skilled person would give the terms in the claim a practical meaning.

Do the claims define a pre-formed seal body?

71. One of the points of dispute between the parties relates to whether the central and side portions of the mask constitute "distinct, clearly defined portions" in the mask.[65] This arose in the context of the ground of novelty, but also impacts on the priority claimed by the applicant. Given that the construction of the specification and claims lies at the heart of the issue, I will consider this point as part of my interpretation of the specification and claims.

72. The gist of the opponent's submissions is that the wording used in the claims imparts some kind of temporal limitation inasmuch as the shape and conformation of the seal is intrinsically linked to it being in place on the patient and in use. In particular, Mr Palkon stated that:

> "In considering claim 1 of the 628 Application, I understand the requirement of 'a central portion ***to extend across the base of the nose***'… and 'each side portion ***extending across a side of the nose***'… to be referring to the location these portions will have ***when the mask is in position on a user's nose, and the seal is under internal pressure***. This understanding is supported by the fact that the claim requires the seal to be formed from a soft flexible material… and have a supple face contacting side to conform under internal pressure to the surfaces of the nose of a wearer... This language contemplates that the seal may not, due to its flexibility and suppleness, have a clearly defined shape relative to the user's nose and face when it is not in place on the user's face and/or under internal pressure, however it will

[64] OS at [61].
[65] Eaton 1 at [305]

engage a user's nose in the way required by the claim once the seal is under internal pressure and brought into conformity with the user's nose" [emphasis added].[66]

73. This statement was made in view of prior art raised by the opponent, and in response to Mr Eaton distinguishing that prior art on the basis that the present mask comprises distinct, clearly defined portions. That is, the interpretation given was essentially a hindsight exercise of whether the terminology used in the claim could be interpreted to include a specific piece of prior art, rather than how the terminology would have been interpreted by the skilled person in view of the common general knowledge at the relevant time. I therefore consider that lesser weight can be given to this evidence in the determination of the meaning of the claim.

74. That aside, I acknowledge that the structure of the mask is certainly defined with reference to the nasal geometry of the user and the function of certain portions of the mask. But I do not consider that the wording of the claim imparts the temporal limitation suggested by Mr Palkon. Rather, the various features of the masks are distinct and clearly defined portions that are present in the mask body *per se*, and that, in use, are shaped to be positioned in the way indicated by the claim. The terminology used in the claim (to extend…, to conform…, etc.) simply characterises the features and shape of the mask with reference to facial geometry. Thus, for example, "a central portion to extend across the base of the nose" requires that the central portion must generally be shaped and sized to be able to sit across the base of the user's nose. There is otherwise nothing in the language of the claim or specification to suggest that the seal is essentially shapeless.

75. I also note that the claim defines that the face contacting side of the seal is supple to conform *under internal pressure* to the surfaces of the nose of the wearer. The interpretation given by Mr Palkon requires the use of a frame (or other external means) to push the inflated mask against the surfaces of the face of the user and mould the seal to the required shape (which Mr Palkon refers to as being "brought into conformity"). There is no mention of such means in the specification, and contrary to Mr Palkon's interpretation, I do not consider that this type of arrangement, involving external forces, is contemplated by the language used in the specification and claims.

76. In short, I consider that the language of the claim requires that the various portions are pre-formed in the seal body.

Supple

77. My understanding is that the opponent has no formal objections to the terms "supple", though they refer to the term as being vague in scope.[67] Despite this submission, it seems to me that the experts do not differ significantly as to the meaning of the term supple in the context of the invention disclosed. For example, Mr Eaton understood supple to mean the ability to move freely with minimal resistance to force and/or pressure. In the context of CPAP masks, he understood it to mean a surface, material or component likely to deform substantially under forces generated through the provision of positive airway pressure or patient contact. He went on to state that, as used in the specification, "supple" would be understood as being sufficiently soft, compliant, and flexible to conform to the users face in response to positive air pressure,

[66] Palkon 2 at [193].
[67] OS at [26].

while avoiding wrinkling, folding or deformation which could impair the effectiveness of the seal.[68]

78. Mr Palkon similarly understood the specification to require something which is sufficiently flexible that it will deform under the usual pressure of the CPAP mask, but not so flexible that it collapses either under atmospheric conditions or when subjected to the pressures usually experienced by a CPAP mask. The specification lists a range of materials and thicknesses of materials that can be used to form the supple portions of the mask. Mr Palkon noted that these materials differ in hardness and some, such as silicone, are available in different hardnesses. The range of thickness will also impact on the ability of the material to deform.[69] Mr Palkon stated that he therefore could not determine what is required for the portion of the seal to be considered supple.[70]

79. Mr Palkon's concerns appear to be directed at being able to determine the materials and properties that would be capable of achieving the desired outcomes, rather than the meaning of the term "supple" *per se*. Notwithstanding this concern, the claim does not use the term in isolation but rather defines that the material is "supple to conform under internal pressure to the surfaces of the nose". That is, the term is linked to a particular function and the conditions under which that function is achieved. The meaning of terms is also determined with reference to the skilled person and the common general knowledge in the art. Both experts were aware of inflatable (and pressure-assisted) seals, and it would therefore seem reasonable to me that they would also be aware of suitable materials for such seals. Moreover, the opponent did not raise this issue (or indeed any issue) under the ground of sufficiency, so it may be assumed that they consider the specification provides a clear enough and complete enough disclosure in that regard.

80. Turning now to the specific terms used in each of the different applications:

Claim 1 of '628

81. Claim 1 of '628 is directed to an *inflatable nasal seal for a patient interface*. In addition to the features set out above, the claim defines that:

> "an exterior side of the seal including regions much stiffer than the supple interior side, the regions extending into the side portions of the seal."

82. I understand the reference to interior and exterior sides to mean that the inflatable seals defined by the claims consist of a hollow body assembly. The patient-facing side corresponds to the section of the wall of the hollow seal body bounded by the parts of the seal contacting the patient's face. The external portion of the mask corresponds to the walls of the seal that are outside of that boundary. The invention is further characterised by the configuration of the exterior side (or wall) of the seal body to incorporate regions that are defined to be *much stiffer* than the supple interior side of the mask. The evidence suggests that the incorporation of reinforcing features such as ribs was routine if regions of the mask required greater rigidity, but the opponent made submissions on the clarity of the term "much stiffer" and "extending into the side portions". I have discussed these in detail below.

Claim 1 of '838

---

[68] Eaton 1 at [121] to [125].
[69] Palkon 1 at [172].
[70] Palkon 1 at [172].

83. Claim 1 of '838 is directed to a *nasal seal for a patient interface*. In addition to the features set out above, the claim defines:

> "wherein the side portions each include an outward face portion and an inward face portion and a peripheral edge portion that joins the inward face portion and the outward face portion."

84. Mr Palkon considered that the wording of this feature was an attempt to identify sub-portions of the side portion, but he could not determine where each of the portions began or ended.[71] On the other hand, Mr Eaton understood the peripheral edge portion to be the point at which the two face portions meet. He referred to the peripheral section of the mask shown in Figure 15 to illustrate this interpretation, and highlighted the exterior portion in red, the face contacting portion in green, and the peripheral portion in blue.[72]

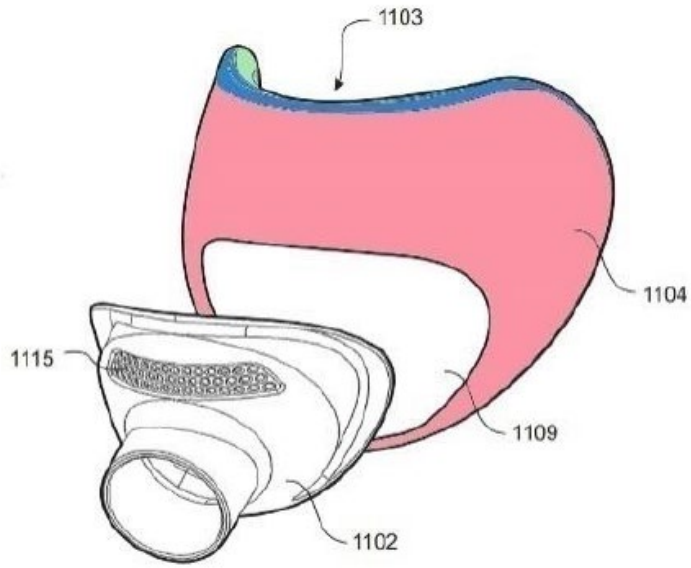


FIG. 15

85. I agree with the meaning provided by Mr Eaton. The peripheral portion is a distinct region on the outer edges of the surface which demarcates the inward and outward faces. That is, the arrangement results in three distinct areas or surfaces – one which faces in the direction of the patient (the inward facing portion), one that faces away from the patient (the outwards facing portion), and an intermediate edge portion joining the opposing surfaces. I consider that the skilled person would be able to give this practical meaning.

Claim 1 of '840

86. Claim 1 is directed to a *patient interface* that is characterised by the nasal seal that includes the features set out above, it further defines that:

> "an exterior side of the seal including regions much stiffer than the supple interior side, the regions extending into the side portions of the seal,

[71] Palkon 1 at [357] to [358].
[72] Eaton 1 at [280].

> a mask body assembled to the seal, the mask body formed of a material more rigid than the seal,
>
> and together with the seal forming an enclosure having an inlet opening and a patient outlet opening."

87. There was no real dispute between the parties that Claim 1 of '840 is directed to the patient interface as a whole, which would include the seal and the mask body, but also other components such as the headgear, which would be required by the patient in use. Like '838, '840 does not define the seal to be inflatable but includes the feature that the seal conforms under internal pressure to the surfaces of the nose. Like '628, the seal is defined to include regions made of a much stiffer material than the supple material in the inner face.

88. Claim 1 of '840 further includes the definition of the mask body, which includes that the mask is made of a material that is more rigid than the seal. Mr Palkon stated that all masks he was aware of as at 2006 had a mask body that was made of a harder material than the seal, and therefore more rigid. They also had an inlet opening to provide gas to the mask, and an outlet opening for gas to be provided to the patient.[73] I note that Mr Eaton stated, and I understand it to have been conceded by Mr Palkon, that not *all* patient interfaces contain a mask body and, further, not all mask bodies are formed of a material more rigid than the seal. For example, cannula style interfaces do not necessarily have a mask body/frame arrangement.[74] This does not impact significantly on the interpretation of the claims since they are limited to where a mask body is present.

Claim 1 of '842

89. Claim 1 is directed to a *nasal seal for a patient interface*. In addition to the features set out above, it defines:

> "wherein a peripheral portion of the seal joining the face contacting side to the exterior side, is supple and allows the interior side of the seal to displace relative to the exterior side."

90. Like '838, the claim defines a peripheral portion of the seal that joins the face-contacting and exterior sides of the seal. In '842 the peripheral portion is further characterised by the seal being configured to enable the inner surface to displace relative to the outer face. Mr Eaton stated that the function of the peripheral portion is to decouple the outward and inward face portions and create a rolling bellows configuration within the pressurised part of the seal. This enhances displacement of the supple, interior side of the seal relative to the stiffer, exterior side while ensuring that the interior side does not displace relative to the user's face. This ensures the mask conforms to the user's face while maintaining an effective, leak-free seal.[75]

Claim 1 of '843

91. Claim 1 is directed to an *assembly for a patient interface* which comprises a nasal seal having the features set out above. The claim further defines:

> "an exterior side of the seal including regions much stiffer than the supple interior side, the regions extending into the side portions of the seal,

---

[73] Palkon 1 at [369].
[74] Eaton at [246].
[75] Eaton 1 at [228].

the seal includes an extension to go over the user's mouth, and a mask body assembled to the seal, the mask body formed of a material more rigid than the seal, and together with the seal forming an enclosure having an inlet opening and a patient outlet opening."

92. Similar terms are used to define the invention in '843 as discussed above, and a similar construction applies here. The additional feature of '843 relates to the further inclusion in the patient interface of an extension to go over the user's mouth. There was no dispute as to the meaning of the claim in this regard.

Claim 1 of '841

93. The claim is directed to a *patient interface* that comprises an inflatable nasal seal, and is further characterised by:

> "a mask body connected to the seal, including a seal engaging portion that engages an exterior side of the seal, a mask body inlet opening and at least two strap engaging portions,
>
> each strap engaging portion extending laterally away from the mask body inlet opening, from opposite sides of the mask body inlet opening".

94. Notably, Claim 1 is characterised by the inclusion of an inflatable nasal seal, and by side portions that at least extend across a side of the nose. However, '841 differs from the other applications in that the claim does not include the feature of the "face contacting side of the seal being supple to conform under internal pressure to the surfaces of the nose of a wearer, including, at the side portions of the seal, to outside surfaces of the sides of the nose".

95. Besides the terms already discussed above, there was no apparent dispute between the experts as to the meaning of the terms used in Claim 1 of '841.

Priority considerations

96. As noted above, the present applications are members of a family of related patents and applications. Present applications '838, '840, '841, '842 and '843 are divisional applications of '628.

97. Another application, 2021240146, is also a divisional of '628. Application 2021273595 is a divisional of 2021240146. These two applications are the subject of opposition proceedings but have yet to progress to hearing.

98. Application '628 is itself one in a series of divisional applications originating with 2010246985:

Application	**Filing date**
2019200263	16 January 2019
2017200991	14 February 2017
2016204384	27 June 2016
2015202814	25 May 2015
2010246985	10 May 2010

99. The original application (2010246985) was filed under the Patent Cooperation Treaty (PCT) as application number PCT/IB2010/052061. It claimed priority from two earlier applications: PCT/NZ2009/000072 (**'072**) filed on 12 May 2009, and US 61/260590 (**'590**) filed on 12 November 2009. Notably '072 claims priority from an earlier application, US 60/052362, which was filed on 12 May 2008.[76]

100. The opponent submitted that each of the present applications claims priority by reference to their parent application(s), and therefore rely on regulation 3.13D. The priority of the applications ultimately leads back to 2010246985. As this application was filed on 10 May 2010, the pre-RTB regulations apply. The gist of the opponent's submissions is that the present applications cannot rely on the basic applications '072 and '590 for earlier priority since these were not the first applications for the present invention in a convention country. The basic application '072 claims priority from an earlier application which was filed more than 12 months before 2010246985. The opponent argued that the consequence is that the present applications cannot claim a priority date earlier than 10 May 2010 (the filing date in Australia of 2010246985).

101. The relevant law that applied at the time the original application was filed (10 May 2010) was set out in subsection 94(1) as follows:

> A Convention applicant in relation to a basic application may make a Convention application or 2 or more such applicants may make a joint Convention application, within the prescribed period.

102. The prescribed period was set out in Regulation 8.5(2) as 12 months from the day on which a basic application is first made in a Convention country in respect of the invention. Where an earlier application was made for the invention more than 12 months before the filing date of the Convention application, Section 96(1) provided for that earlier application to be disregarded under certain circumstances:

> (1) Where, at the time when a Convention application is made in respect of an invention:
>
> (a) an application has been made for protection in respect of the invention in a Convention country; and
>
> (b) the application has been withdrawn, abandoned or refused without becoming open to public inspection; and
>
> (c) the application has not been used as the basis of claiming a right of priority in a Convention country under a law of that country corresponding to this Part; and
>
> (d) a later application has been made by the same applicant for protection in respect of the invention in the Convention country in which the earlier application was made;

[76] Another Australian application, 2010241390, was filed as a divisional of '072, and also claimed convention priority from several other basic applications, including PCT application PCT/IB2010/052061 from which 2010246985 derives. AU 2010241390 lapsed following examination. Australian application 2009247053 is the Australian application corresponding to PCT/NZ2009/000072, having the earliest priority of 12 May 2008. It was published on 19 November 2009 but lapsed as it did not enter the national phase within the required time. Neither of these applications are an issue in the present matter.

the applicant may ask the Commissioner to disregard the earlier application for the purposes of this Part.

103. Notably, Section 96(1) required that all the conditions set out in (a) to (d) must be met for the applicant to make a request that the earlier application be disregarded. The opponent noted that no request had been made for the earlier application to be disregarded in the present case. The opponent also noted that the earlier application (US 60/052362) had been used as the basis of claiming right of priority for PCT/NZ2009/000072 and therefore would not have met the requirements of section 96(1) in any case.[77]

104. Section 96(1) refers to a Convention application made in respect of *an invention*, and an (earlier) application made for protection in respect of *the invention* in a Convention country. Similarly, regulation 8.5(2) refers to the first application in a convention country in respect of *the invention*. This essentially requires that the invention that is the subject matter of the Convention application is the *same invention* as that disclosed in the earlier application.

105. The present situation also involves multiple priority documents and, potentially, multiple priority dates. For simplicity I have attempted to condense the relevant considerations into the following general example where multiple applications are filed:

Application 1 Invention A

Application 2 Invention A and Invention B

Application 3 Invention B

106. In this case, application 2 could validly claim priority from Application 1 for invention A, provided that application was made within 12 months of the earlier application.

107. If application 2 disclosed additional subject matter (invention B) to that disclosed in the first earlier application (which only described invention A), then this would be the first application in a convention country for invention B.

108. A subsequent convention application (application 3) could make a valid priority claim for invention B based on the first disclosure of that invention in application 2, provided application 3 was made within 12 months of the date on which application 2 was filed. The key consideration is whether invention B is the *same* invention as invention A.

109. At the hearing the opponent submitted that the definition of the term "invention" as used in the legislation should be taken to be that set out by the High Court in *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd*. Section 40(2), as it existed at the time, required that the complete specification describe the invention fully, as well as end with a claim or claims defining the invention. The Court referred the various meanings given to the term "invention" before stating that the correct meaning for the purposes of section 40(2) was:

[77] OS at [78].

> "The embodiment which is described, and around which the claims are drawn. This is the sense used in the Act: *cf.* the phrase of s 32, 'the invention so far as claimed in any claim.'"[78]

110. Where a claim of a Convention application was fairly based on matter disclosed in a basic document that was lodged more than 12 months before the filing date of the Convention application, the practice under the Pre-RTB Act was that the priority date was taken to be the date of filing of the Convention application.[79] This fair basis consideration required a "real and reasonably clear" disclosure of the invention in the priority document. Under the *RTB Act* a valid priority claim requires the earlier priority document to disclose the invention in a manner that is clear enough and complete enough for the invention to be performed by the person skilled in the art.

111. The differences in the legislation do not impact on the present consideration since, as detailed below, I do not consider the invention(s) claimed in the present applications were disclosed in the earlier application (whether under RTB or pre-RTB). In making that assessment, the consideration is whether the invention in the later application is the *same* as the invention disclosed in the earlier application. A key consideration is whether all of the features of the invention claimed in the later application were disclosed in the earlier application.

112. In the broadest sense, the earlier application (US 60/052362) disclosed:

> "a patient interface comprising a supple envelope, bag or balloon, with an air supply aperture and a pair of protruding nostril locators protruding from the envelope, each nasal locator including an outlet aperture, the envelope, bag or balloon inflating under internal pressure from a pressurised gases supply and when pressed against the face of a user, creating a seal with the nose or face of the user in addition to any seal provided by the nasal locators."[80]

113. The earlier application goes on to state that the body of the envelope, in use, forms a substantially continuous seal against the user's nose and face that surrounds the nostril locators, more specifically, the nose, upper lip and the cheeks.[81] When inflated the envelope is said to have a general blob shape, and is so supple that it does not hold its shape.

114. The figures below illustrate the manner in which the seal body inflates to form the seal with the user's nose and face. The seal body is said to broadly be shaped to have a sidewall (108) and a seal surface (110). In use, either or both of these press against the user's face to form a seal that conforms around the nose and surrounds of the nostril locators.[82]

---

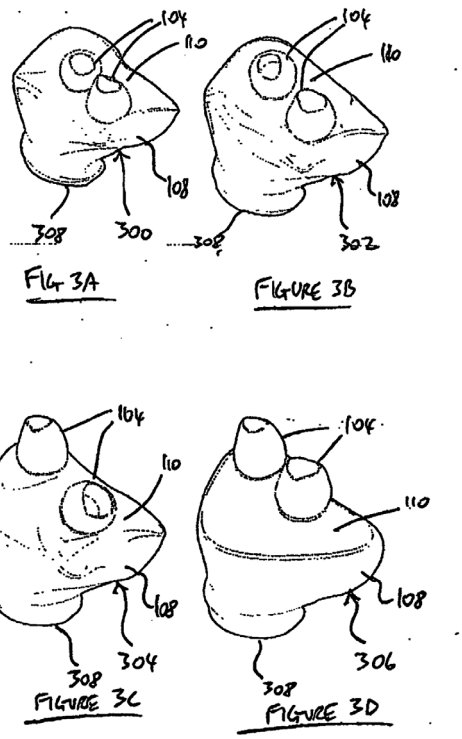
[78] [2001] HCA 8 at 21. Note that the reference to section 32 relates to the UK Patents Act 1949, which used the same expression as section 18(1) of the Australian Patents Act: *"an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim…"*

[79] Patent Manual of Practice and Procedure, current version 8.11.3.

[80] US 60/052362 at page 2, lines 11 to 15.

[81] US 60/052362 at page 4, lines 1 to 2.

[82] US 60/052362 at page 5, lines 19 to 32.



115. The seal is used together with a frame that presses the inflated seal body against the face of the user right out to the periphery of the frame. A nasal ridge of the frame may press the uppermost periphery of the compressed seal against the ridge of the user's nose, and side peripheral portions of the frame may press the side peripheral portions of the seal body against the lower cheeks of the user.[83]

116. The '072 priority document discloses two embodiments. The first embodiment corresponds to the invention described in the earlier application. The second embodiment relates to an alternative seal that the applicant submitted is the crux of the present inventions. In particular, Figures 10 to 12 (which correspond to Figures 10 to 12 of the present applications) depict a seal body which is *shaped* to wrap around the user's nose. The seal body is said to have side portions or wings that extend completely over the sides of the user's nose and may also extend partially over the user's cheeks.[84] In use the gases inflate the seal body and cause it to press against and about the user's nose. The nostril locators are caused to seal in or about the user's nose and the pressurised gases pass through the locators into the user's nostrils.[85] The application goes on to state that:

> "The seal body is made from a flexible material. Examples of possible materials include latex, vinyl, silicone and polyurethane. In a preferred form the seal body's outer surface is made from a thicker material than the inner surface. In this way the seal body has a better ability to hold a predetermined shape."[86]

[83] US 60/052362 at page 6, lines 17 to 21.
[84] PCT/NZ2009/000072 at page 16, lines 4 to 6.
[85] PCT/NZ2009/000072 at page 16, lines 20 to 24.
[86] PCT/NZ2009/000072 at page 16, lines 29 to 32.

117. It would seem to me that this is the disclosure around which the claims of 201024698 and, in turn, the claims of the present applications are drawn. None of the embodiments described in the earlier application (US 60/052362) comprise a distinct and preformed shape as required by the present claims (as discussed under construction), including the central and side portions of the seal, or of other features such as the stiffer regions in the external side of the mask. While the seal of the earlier application may extend to the ridge of the user's nose and cheeks, this is the result of the frame pressing on the relatively amorphous balloon seal to force it outwards to the periphery of the frame rather than any preformed shape in the mask.

118. AU 201024698 was filed within 12 months of '072, which was the first disclosure of the invention comprising the distinct and preformed shape defined by the present claims (in addition to other characterising features defined in claim 1 of each application). I therefore consider that the present applications are entitled the earliest priority date of 12 May 2009.

Novelty

119. An invention is taken to be novel when compared with the prior art base unless it is not novel in light of certain types of prior art information, each of which must be considered separately.[87] For the purposes of the present consideration, the following kinds of information are relevant:

- Prior art information made publicly available in a single document or through doing a single act;
- Prior art information made publicly available in 2 or more related documents, or through doing 2 or more related acts, if the relationship between the documents or acts is such that a person skilled in the relevant art would treat them as a single source of that information.

120. It is well-established that the general test for anticipation is the reverse infringement test:

> "The basic test for anticipation or want of novelty is the same as that for infringement and generally one can properly ask oneself whether the alleged anticipation would, if the patent were valid, constitute an infringement."[88]

121. Thus, the test is satisfied if the alleged anticipation discloses all of the essential features of the invention as claimed. Furthermore, as stated by the Full Court in *AstraZeneca v Apotex*:

> "… for a prior art document to be anticipatory, there must be … a clear description of, or clear instructions to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's patent."[89]

122. A classic formulation of this principle was given in *General Tire v Firestone*, which stated that the prior art "must contain clear and unmistakable directions to do what the patentee claims to have invented… a signpost, however clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee."[90]

---

[87] Subsection 7(1) of the Patents Act.
[88] *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* [1977] HCA 19 at [20]; 137 CLR 228 at [235].
[89] *AstraZeneca AB v Apotex Pty Ltd* [2014] FCAFC 99 at [301].
[90] *The General Tire & Rubber Company v The Firestone Tyre and Rubber Company Limited* [1972] RPC 457 at 485-486.

123. The opponent raised a number of citations under the ground of novelty:

D1 US 5,243,971 (Sullivan) published 14 September 1993;

D2 US 2005/0199242 (Matula) published 15 September 2005;

D3 US 5,724,965 (Handke) published 10 March 1998;

D4 US 5,540,233 (Starr) published 30 July 1996.

124. The opponent also relied on certain information made publicly available through the following acts:

U1 Since at least 1996, each public display, sale, offer for sale or use of the Sullivan Bubble Mask;

U2 Since at least 2005, each public display, sale, offer for sale or use of the Respironics ComfortCurve™;

U3 Since at least 2000, each public display, sale, offer for sale or use of the Respironics Monarch Mini.

125. The opponent also relied on the following documents pursuant to the present application having a deferred priority date of 12 November 2009.

D9 US 2009/0120442 (Ho) published 14 May 2009.

126. I have determined that the priority claim of 12 May 2009 is valid. This pre-dates the publication date of D9. I therefore do not consider that D9 is relevant to the ground of novelty (or inventive step) and have not considered this document any further below.

Document D1 (Sullivan)

127. D1, which is also referred to in the evidence as "Sullivan", discloses nasal masks that are suitable for use with CPAP machines. The nasal masks comprise a membrane which defines a chamber, the membrane being formed from an elastomeric material and the chamber having a thin walled externally convex end region which is arranged in use to be depressed by, and to accommodate, the nose of the wearer.

128. Two different configurations of mask are disclosed. The opponent's submissions did not specifically refer to the first embodiment, but the opponent confirmed at the hearing that both embodiments were pressed. The first type of mask (Figures 6 and 7 below) uses an inflatable membrane (13) with nipples (41) that are inserted into the nostrils.

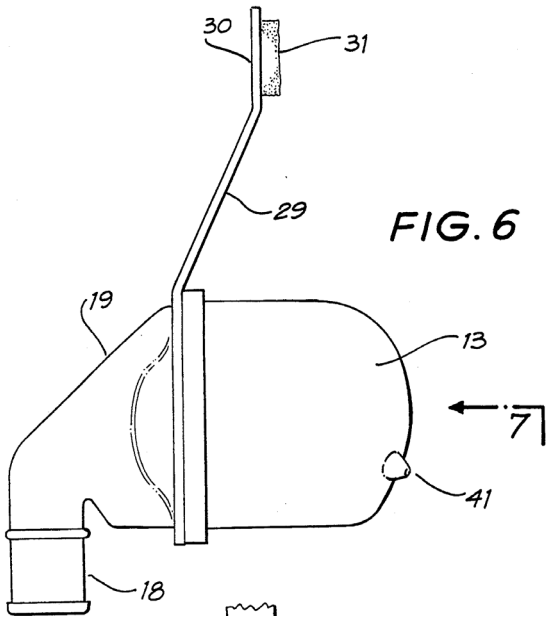


FIG. 6

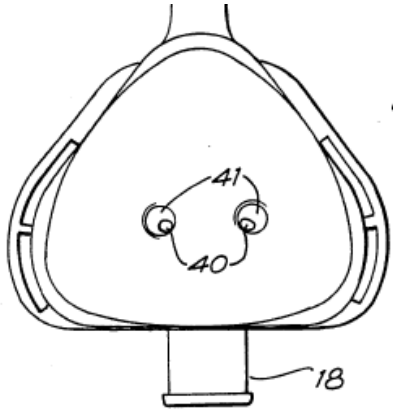


FIG. 7

129. In use, the mask is connected to the pressurised air supply so that the membrane distends outwardly from the shell. The face contacting portion of the mask is placed in contact with the user's face and positioned so that the nipples align with the user's nasal passages. The inflated mask is pushed onto the face which moulds the membrane to the facial contours of the user.

130. I consider I can deal with this particular embodiment fairly briefly, as the consideration goes to the same issues that I have already dealt with separately under construction and priority. In particular, I have construed the claims to define masks in which the central and side portions are pre-formed in the mask body. This is not disclosed by the first embodiment described in D1.

131. The second embodiment disclosed by D1 also comprises a membrane formed from a soft, flexible plastic. Figures 2 and 3 provide front and side views of the mask, while Figure 5 gives a cross section view along the section plane 5-5 indicated in Figure 3. An aperture (39) is formed in the membrane (13). The aperture is shaped to provide an air passage to the user's nasal passages. The shell body portion (24), to which the air supply, harness and upper head engaging portion (30) are connected, engages with the connector moulding (27) via the shell lip (26) and recess (35). The moulding (27) can be configured to provide support for the membrane (13), or alternatively the moulding may be formed integrally with the membrane. The moulding shown in Figure 5 above is formed separately of the membrane and includes an integral wall (36) which is profiled at (37) to locate around the nasal bridge of the wearer, and at region (38) to fit against the upper lip of the wearer. Mr Palkon took the moulding (27) and flange (34) to be the exterior side of the seal which includes stiffer regions.[91]

[91] Exhibit DJP-11, integer 1.11.

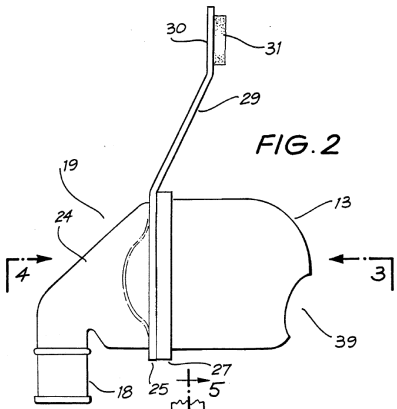


FIG. 2

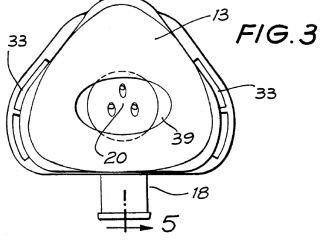


FIG. 3

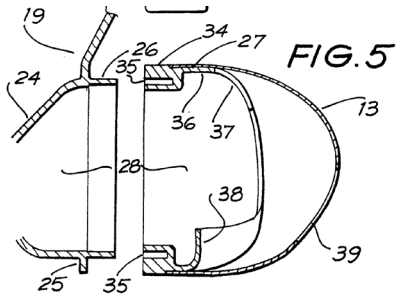


FIG. 5

132. The mask operates much the same as the first embodiment in that the user's nose is aligned with the aperture and the mask is moved to contact the user's face. The aperture is adjacent the air orifices (20). The mask is held in its final position by the headgear as shown in Figure 8C below.

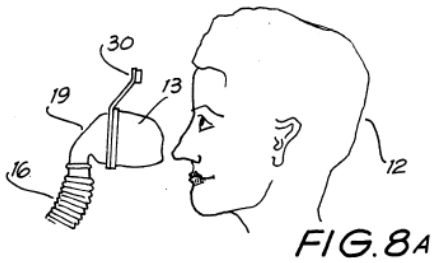


FIG. 8A

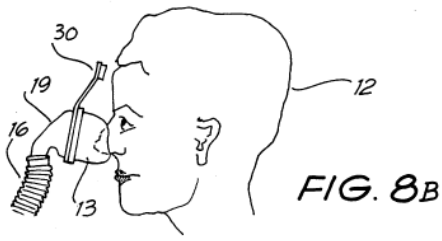


FIG. 8B

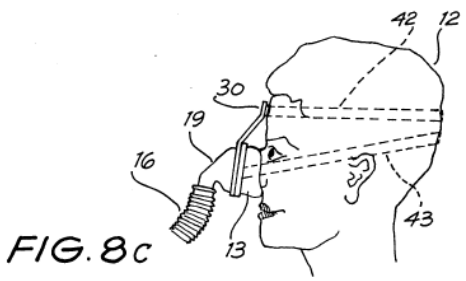


FIG. 8C

133. Mr Palkon provided a comparison of the features of the claim and what he considered was the corresponding disclosure in the specification.[92] Despite his difficulties in determining the meaning of the terms, he identified a portion of the seal that could be described as central and that extends across the base of the nose, indicated by the orange lines below.

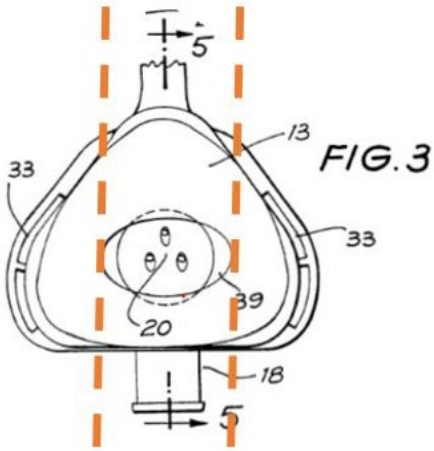


FIG. 3

134. Having identified the central portion as shown, Mr Palkon considered that the regions on each side of the central portion could be described as a side portion. He stated that these extend across a side of the nose when positioned on the face of the user and moulded around their nose.[93] The applicant considered this an artificial exercise that ignores the teaching in D1 that the seal does not have a specific shape, unlike the present invention.[94] At the hearing they further submitted that D1 does not provide clear and unmistakable directions to the present invention in that the specific positioning of the mask against the nose cannot be gleaned from the specification or from the figures.

135. To a large extent the consideration here is much the same as for the first embodiment. Mr Palkon has identified a region of the mask that *could* be considered a central portion, but the side portions are only made to conform to the sides of the nose by the action of pressing the inflated mask against the face, rather than by internal pressure inflation of the seal. Absent such actions, the side portions concave away from the user's face.[95] I also share the concerns of the applicant regarding whether D1 provides clear and unmistakable directions in relation to the placement of the mask. My understanding is that, in use, the wearer's nose sits within the aperture and the membrane lies across the area between the upper lip and the base of the nose. This is indicated in Figure 5 above, where the wearer's upper lip region is pressed against the inner wall at (38). This would result in the user's nose being positioned further into the body of the mask. In such a configuration, the seal does not consist of a central portion that extends across the base of the nose. Rather the base of the nose lies within the mask body and (presumably) adjacent to the lower wall of the mask shell rather than the face contacting side of the seal.

136. Furthermore, in this position the sides portions of the seal do not appear to extend from the sides of the base of the nose, but rather from the upper lip area and around the nose. But because

[92] Exhibit DJP-11.
[93] Palkon 2 at [191].
[94] AS at [75].
[95] Eaton 1 at [309].

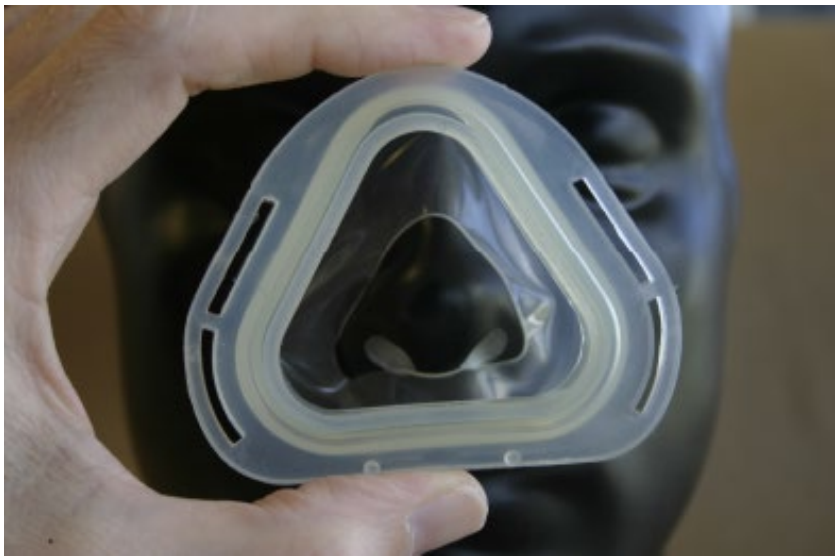
D1 does not provide specific details as to how the mask is positioned on the user's face, I am unable to determine with any certainty how the different portions of the Sullivan mask are positioned on the user's nose.

137. In summary, I am not satisfied that the features of the claims of the present applications are disclosed by D1. The claims of each of the opposed applications are therefore novel in view of D1.

U1 – the Sullivan bubble mask

138. The features of the Sullivan bubble mask correspond to the features shown in D1, and, as a consequence, the opponent's submissions for U1 are much the same as those made for D1.[96] The opponent also relied on photographs of a sample mask, as well as a promotional brochure and user instructions.[97] The applicant does not appear to dispute the availability of the Sullivan bubble mask prior to the earliest priority date, and Mr Eaton also stated that he was aware of the mask before that time.[98]

139. The key additional material provided in relation to U1 includes photographs showing the bubble mask being held up against a manikin face,[99] which appear to be more recent but are relied on by the opponent in their prior use submissions.[100] One of these images is shown below:



140. Mr Palkon stated that

> "In the photos of the Sullivan Bubble Mask, I see what appears to be a seal which will fit over a patient's nose. There is a membrane on the face contacting side of the product. This membrane appears "floppy" and does not appear to hold a fixed shape. Based on this I understand that the membrane is thin and flexible. Based on this, I understand from the photos that when the seal is placed over a user's nose, and pressurised air is introduced

[96] OS at [104].
[97] Exhibits RLS-33, RLS-39, RLS-40 and MC-2.
[98] Eaton 1 at [503].
[99] Exhibit MC-2.
[100] Other photographs showing a mask fitted to a patient were provided, but none provide a clear view of how the mask seal interacts with the patients face.

> through the conduit in the rear of the device, the seal will inflate and press against the user's face around their nose."[101]

141. Mr Eaton noted that mask was typical of the flat, planar style of masks used in the early 2000s. The mask has a triangular, generally convex shape with near vertical edges forming the triangular shape. He described it as being blunt and blocky, a very mechanical design and not contoured to the user's face.[102] He went on to note that the photographs show the mask cushion in isolation without any air supply or internal pressure. This means that the mask is not fitting as it would when pressurised, even leaving aside the question of whether this was an appropriate size mask for the manikin.[103] He went on to state that:

> "Nonetheless, even without seeing the mask cushion in its pressurised state, the photograph indicates that the lower part of the mask cushion rests on the face above the upper lip and below the nose, with the perimeter then curving around the sides of the lower cheek, up around the cheek portions beside the nose and across the bridge of the nose. There is nothing in the photograph that indicates that the mask cushion has a central portion which extends across the base of the nose and a side portion extending from each end of the central portion which ends across a side of the nose."[104]

142. The applicant submitted that it is not insertion of the nose into the central portion of the mask that causes the mask to seal. Rather the placement of the mask over the nose and onto the user's upper lip and side portions of the face next to the sides of the nose gives the seal.[105] As explained by Mr Eaton, the mask "would form a large perimeter surrounding the user's nose, rather than curving or contouring to the user's nose".[106]

143. On balance I agree with the case forwarded by the applicant. The opponent's case was predicated on the various features of the invention being provided during use. The photographs show the mask in an uninflated form (in the above photograph) and physically pushed on to the user's nose, rather than preformed portions of the seal being made to conform to the user's nose by internal pressure in the mask. Absent this exterior force the seal concaves away from the user's face. Setting aside the issue that the photographs show the mask placed or held, rather than fitted, on the manikin's face, the patient facing side of the seal does not extend across the base of the nose. Rather, placement of the nose within the seal body, as shown in the photographs, results in the seal extending across the upper lip below the nose – that is, the central portion extends *along*, rather than *across*, the base of the nose.

144. To the extent that the photo of the mask in place on the manikin could be said to show that the bubble seal somehow extends to the base of the nose, I do not consider that the opponent has made their case on this point. It appears that the edges of the orifice are positioned below the base of the nose and around the flanks of the ala. If there is any portion of the seal in contact with the base of the nose, this would appear to a *de minimis* contact and hardly one which would be considered as extending across the base of the nose.

145. In short, I am not satisfied that the material provided in support of the prior use of the Sullivan bubble mask discloses all of the features of the present claims. I therefore do not consider that

---

[101] DJP-41, integer 1.1.
[102] Eaton 1 at [504].
[103] Eaton 1 at [509].
[104] Eaton 1 at [510].
[105] AS at [86].
[106] Eaton 1 at [514].

the additional information provided for U1 results in a different outcome to that made for D1. For similar reasons to those given for D1 above, the claims of each of the present applications are novel in view of U1.

Document D2 (Matula)

146. Document D2 (also referred to as "Matula" in evidence) describes a patient interface on which the Respironics ComfortCurve™ product is apparently based.[107]

147. The experts differed significantly as to what D2 discloses. Mr Eaton stated that the objective in developing the ComfortCurve™ product was to create a mask that was small enough not to obstruct a large portion of the patient's face when in use, had minimally sized parts, and was sufficiently stable and adjustable to fit a broad range of face types. The focus was on providing a comfortable support structure for the seal rather than the seal itself.[108] There was no disclosure regarding the wall thickness or configuration of the seal, and the reader was only directed to conventional seals used at that time.[109]

148. On the other hand, Mr Palkon considered that D2 discloses inflatable nasal seals. He stated that:

> "Paragraph [0061] and Figs 2 and 3 disclose this to me. These describe a sealing assembly with a cushion type seal that engages a user's nose, can be made of a unitary material such as silicone, and includes features associated with conventional seals. Figure 3 in particular shows me what the seal will look like and how it will behave. Based on my knowledge and experience as at 2006, I understand that the mask in Figure 3 will behave as follows. The face contacting side will be formed of a relatively thin layer of material, so that when the seal is subjected to internal pressure the face contacting side of the seal is pressed against the user's face. In this way, a cushion is formed by the inflation of the seal.
>
> An additional embodiment is described in [0133]-[0134] and Figs 44 and 45. This includes an inflatable bladder 458 which may be coupled directly to a sealing assembly 460, and which can rest directly on the surfaces of a patient. Paragraph [0133] states that in the illustrated embodiment the sealing assembly is a pair of nasal prongs. However it also states that other types of sealing assemblies, such as a cushion, can be used. As the opening lines of [0133] state that this embodiment is 'according to the principles of the present invention'. I therefore understand that this paragraph contemplates a cushion seal (such as described in paragraph [0061]) being used in combination with the inflatable bladder 458, in place of nasal prongs. This confirms my understanding that the cushion seal in paragraph [0061] and Fig 3 is inflatable as I describe above. Furthermore, an arrangement in which this type of cushion seal was combined with an inflatable bladder (as described in paragraph [0133]) would also be an inflatable nasal seal."[110]

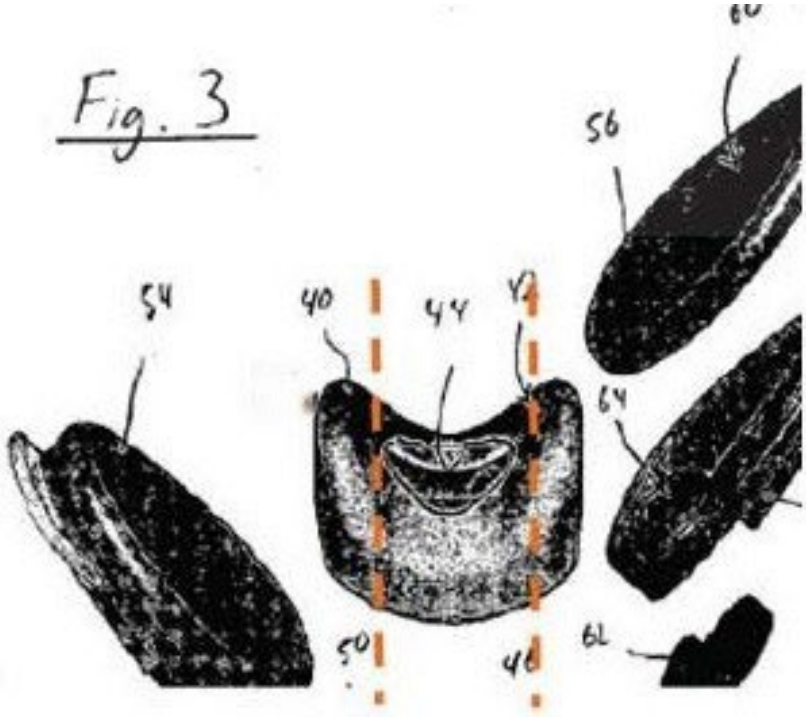
149. On balance I prefer the evidence provided by Mr Eaton on this point. Notably, D2 does not refer to the seals used in the patient interface as inflatable, or even pressure-activated. Mr Palkon infers this from Figure 3, and while the description at paragraph [61] refers to the seal being a cushion type made of a material including silicone, there is no explicit disclosure of inflatable seals or to materials that are sufficiently "supple" to distend under internal pressure

[107] Eaton 1 at [328].
[108] Eaton 1 at [330].
[109] Eaton 1 at [336].
[110] Exhibit DJP-17, integer 1.1.

in use. Silicone is available in different hardnesses,[111] so it does not automatically follow that the reference to silicone infers that the cushion is inflatable.

150. This is also apparent from Mr Palkon's statements in relation to the embodiment discussed at paragraphs [0133] to [0134]. In particular, Mr Palkon's relies on the statement "according to the principles of the present invention", together with the disclosure at paragraph [61] and the feature of an inflatable bladder *positioned in a support member* that spans the user's face, rather than the nasal seal, to conclude that D2 discloses an inflatable nasal seal. The support member containing the inflatable bladder may be connected to the nasal seal, but there is no teaching that the nasal seal portion is itself inflatable or that it is of a construction that is supple to conform under internal pressure to the outside surfaces of the nose. In short, I do not consider that D2 provides a clear and unmistakable disclosure of inflatable nasal seals.

151. Even if I am wrong on this point, I do not consider that D2 discloses other features of the present claims. In this regard, the placement of the seal on the user's face was a significant point of difference between the parties in their submissions. Mr Palkon identified a central portion of the mask in Figure 3 as shown by the orange dashed line below:



152. Mr Palkon had previously stated that he found it difficult to understand what constituted the side portions extending from each end of the central portion, but having identified the central portion as shown above, he considered there is a portion on each end of the central portion that could be described as a side portion extending across the side of the nose.[112] My understanding of the opponent's submissions at the hearing is that in all of the prior art raised, including D2, the user's nose is positioned *inside*, rather than above the seal body in the manner which I understand is the way in which nasal pillows masks are usually positioned.

[111] Palkon 1 at [172].
[112] Exhibit DJP-17, integers 1.5 and 1.6.

153. The opponent also noted that Figure 43 of D2 shows a sealing assembly that extends around the lower portion of the user's nose (labelled as 440 in the figure below).[113]

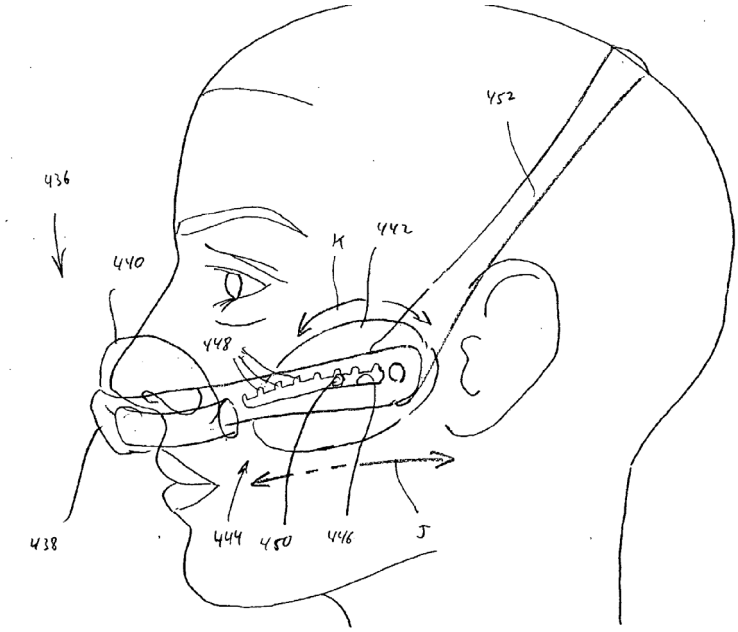


Fig. 43

154. In contrast, the applicant submitted that the seal is intended to be fitted *to the base* of the nose together with a pair of patient-contacting members to support the frame on the patient's face. These overlay the user's cheekbones. The width of the seal is shown as the concave surface which is curved in a way which generally matches the curvature of the alar base of the user's nose (see Figure 3 above).[114] They argued that D2 does not disclose any side portions extending away from the ends of the central portion, let alone portions that extend across the sides of the nose.[115]

155. On balance I prefer the applicant's submissions. Admittedly Figure 43 does appear to show a seal that wraps around the sides of the nose. However, there is no explicit disclosure that this comprises an inflatable, or even pressure-activated, seal arrangement. The specific arrangement about the user's nose is also not apparent from the diagram, and there is no explanation provided in D2 in this regard.[116] To the contrary, and consistent with Mr Eaton's statements, the focus of the disclosure relates to the assembly holding the seal in place.

156. A similar consideration applies to the seal shown in Figure 3. Even if the convex seals referred to by the opponent could be considered as extending across the sides of the nose, there is nothing that suggests that the seal material adjacent to the surfaces of the nose is made of a "supple" material that enables the sides of the seal to conform to the surfaces of the sides of the nose. The particular position of the seal on the user's face also cannot be gleaned from the disclosure. Given the significant differences between the parties as to how the mask is intended to be

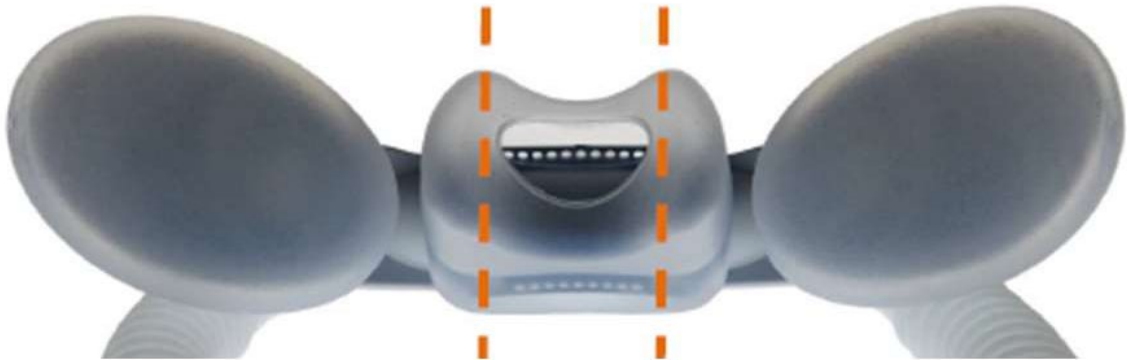
[113] D2 at [0131].
[114] Eaton 1 at [355].
[115] AS at [128].
[116] D2 at [0131] to [0132].

positioned in use, I do not consider there are clear and unmistakable directions in any particular regard. However, it would seem to me that if the user's nose is positioned within the seal, then the feature of the central portion extending across the base of the nose, as well as the consequential feature of the side portions extending from the ends of the central portion across the sides of the nose, is not disclosed by D2.

157. I therefore consider the claims of the present applications are novel in view of D2.

U2 – the Respironics ComfortCurve™ Mask (including the requests pursuant to Regulation 5.23)

158. The Respironics ComfortCurve™ mask is apparently based on the invention disclosed in D2.[117] The disclosure of this product prior to the priority date of the present applications does not appear to be in dispute. The key arguments were much the same as those for D2, but additional photographic material was provided showing the way in which the mask was positioned on a user's face. As with D2, Mr Palkon identified a central portion of the ComfortCurve™ that corresponds with the width of the user's nose.[118] This is shown by the orange dashed lines in the picture below.



159. Having identified that central portion, the side portions were taken to constitute the two ends outside the orange lines. The gist of the opponent's arguments is that these side portions extend across the sides of the nose.

160. I note that Claim 1 of '841 requires that the mask body includes a mask body inlet opening, and that each strap engaging portion extends laterally away from the mask body inlet opening, from opposite sides of the mask body inlet opening. I interpret this to mean that the invention defined by '841 comprises a single mask body inlet. In contrast, the ComfortCurve™ comprises two mask body inlets positioned on each side of the mask. U2 is therefore not relevant to the novelty of '841.

161. Turning now to the evidence, the key issue of dispute evidence relates to the way in which the ComfortCurve™ is positioned on a user's face. In his evidence in support, Mr Palkon stated that:

> "In the ComfortCurve™, there is a seal which will fit over a patient's nose. There is a membrane on the face contacting side of the product. This membrane appears to be formed of a silicone material which is soft. I observed it had a thickness of approximately 0.28 mm

[117] OS at [132] citing Eaton 1 at [161].
[118] Exhibit DJP-47, integer 1.4.

on the face contacting side which would also make it flexible. I also observed that it was able to be easily deformed by hand in those parts where the seal was thin.

Based on this, I understand that when the seal is placed over a user's nose, and pressurised air is introduced through the conduit in the rear of the device, the seal will inflate and press against the user's face around their nose."[119]

162. Notably, Mr Palkon stated that the seal fits *over* a patient's nose. At the hearing the opponent also submitted, with reference to the photograph below,[120] that "*it can be seen from this image alone that when the user's nose tip is located into that hole, part of the seal will extend up and over the tip and over the corresponding flanks of the nose*". They submitted that this could also be seen from the position of the seal in the photograph of the mannikin wearing the mask.[121]

163. The evidence provided by the opponent in relation to the ComfortCurve™ included an instruction manual (the ComfortCurve™ manual), but Mr Palkon stated that he did not have regard to the manual when he prepared his evidence.[122] His evidence was based only on the photographs of the ComfortCurve™ provided to him, and the ComfortCurve™ product shown to him by DLA Piper.[123] The photograph of the manikin shown above was provided by Ms

[119] Exhibit DJP-47, integer 1.1.
[120] *Ibid.*
[121] OS at [134] and Exhibit DJP-47, integer 1.6.
[122] Exhibit MC-6.
[123] Palkon 2 at [264].

Crinion, as part of a bundle of photographs held in the ResMed library.[124] Details of the original source of this material do not appear to have been provided.

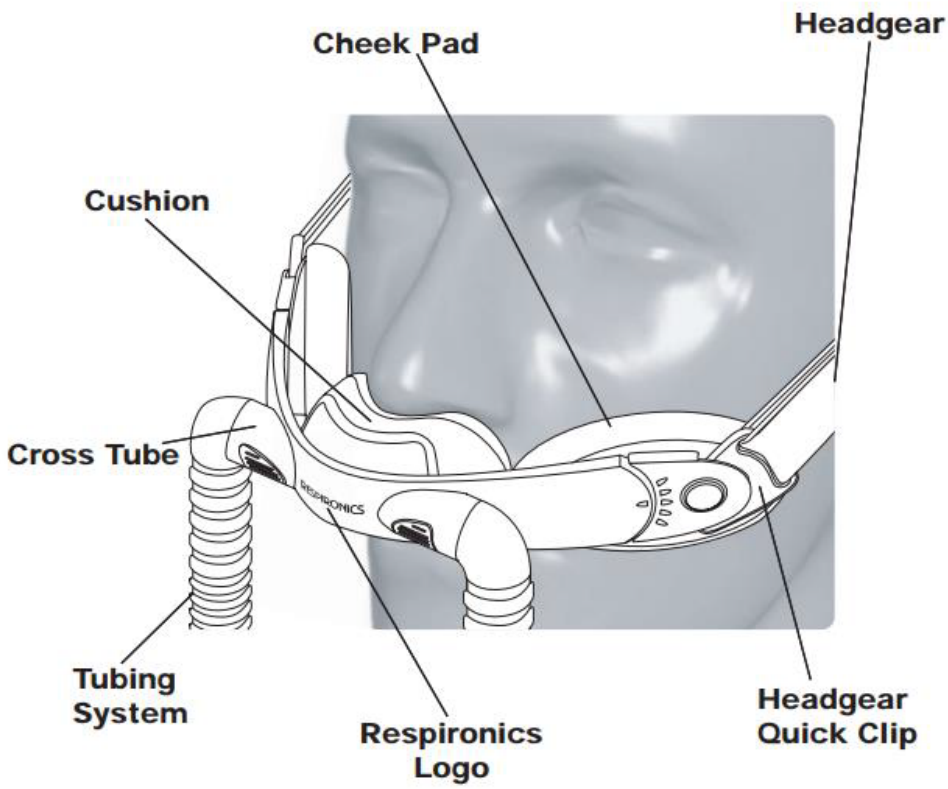
164. The placement of the mask seal was a significant difference in the evidence provided by the experts. Mr Eaton stated that it was difficult to ascertain much from the photographs provided in evidence, including where the seal sits with reference to the user's face and how it interacts with other components of the interface. He instead referred in some detail to the ComfortCurve™ manual, which he said informed the reader as to how the interface is to be connected and worn by the user. The instructions given in the manual include the following:

> "1. Attach the appropriate size cushion to the cross tube of the interface. Press the cushion firmly onto the cross tube until it snaps into place. Pull on the cushion gently to be sure it is completely attached.
>
> 2. If the headgear is attached, place the cheek pads against your cheeks and the cushion **under your nose**. To ensure proper orientation, make sure the Respironics logo is facing up. Pull the headgear over your head.
>
> 3. Adjust the headgear split strap so that the headgear cups the crown of your head. The lower strap should be positioned lower on the back of your head. The upper strap should be placed over the top of your head. Adjust the headgear side straps so the cheek pads and cushion rest snugly against your face. Do not overtighten the headgear. Overtightening can irritate your face, increase leaks, or cause damage to the interface system.
>
> 4. Adjust the angle of the cushion to the proper location **under your nose** by rotating the cheek pads. Rotate each cheek pad upwards or downwards until you reach a comfortable position. Be sure the cushion rests evenly **under the nose**.
>
> 5. Connect the tubing system (included with the ComfortCurve) to the CPAP or bi-level device. Turn on the airflow.
>
> 6. To ensure the best fit, after turning on the airflow, readjust the cheek pad positions as needed so that the cushion provides an adequate seal that minimizes leaks. Lie down in your normal sleeping position and breathe normally. Make any necessary final adjustments to ensure a comfortable and secure seal overnight.
>
> **Note: The ComfortCurve cushion is designed to be placed UNDER your nose. Do not place the tip of your nose inside of the cushion - this may cause unnecessary discomfort and irritation**" [emphasis added].[125]

165. Mr Eaton noted the express instruction (three times, as indicated by the emphasis given above) that the cushion must be placed under the nose and the further note that the tip of the nose should not be placed inside the cushion. He referred to the following figure from the manual, which he said depicts the location of the cushion under the nose and shows the cushion resting evenly along the base of the nose:[126]

---

[124] Crinion at [15].
[125] Eaton 1 at [540], referencing MC-6
[126] Eaton 1 at [541].



166. Mr Palkon did not directly address the ComfortCurve™ manual in his evidence in reply beyond stating that he did not have regard to it in giving his original evidence. Instead, he referred again to the photograph of the ComfortCurve™ in position on a manikin, which he maintained showed that the seal has side portions which extend *"at least somewhat"* across each side of the user's nose. However, he also requested DLA Piper to show him the ComfortCurve™ in position on a person, and to provide him with photographs of the same (shown below).[127]

[127] Palkon 2 at [265] and Exhibit DJP-65.

167. The applicant challenged whether this evidence was properly in reply. They requested, and were given, the opportunity to file evidence responsive to this material (Eaton 2). Mr Eaton again referred to the instructions given in the ComfortCurve™ manual. He also noted that the mask shown in the photograph above was not positioned below the nose, and that the tip of the user's nose was positioned inside the mask cushion.

168. This was a point of some criticism from the opponent, who considered Mr Eaton should have put some other photographs into evidence so as to demonstrate how he considered that it should be correctly worn.[128] But I do not consider this would lead me to draw any adverse findings on the basis that Mr Eaton has not provided any photographic evidence in support of his evidence. Mr Eaton has referred to information that *prima facie* carries a significant weight in determining how the ComfortCurve™ was fitted *at the relevant time*. The opponent bears the onus in the opposition, and it is incumbent on them to adduce evidence that establishes, on the balance of probabilities, that during the alleged prior use of the product, the mask was positioned over the nose rather than the way indicated by the manual.

169. Pursuant to regulation 5.23(2)(c), the opponent filed Sanders 3, Abhyankar and Palkon 3 in response to Eaton 2. The evidence included photographs showed a ComfortCurve™ mask being fitted and held against Ms Sanders' face by Ms Abhyankar. The applicant disputed this evidence (with the exception of Palkon 3, paragraphs 1 to 7 and 13 to 15), but at the same time filed Eaton 3 together with a request that it be considered pursuant regulation 5.23. As noted in the background, no direction has been made concerning this evidence being regarded in the opposition. The delegate had proposed that regard be given to only Palkon 3, paragraphs 1 to 7 and 13 to 15, and deferred further consideration of the other material to the hearing.

170. At the hearing the opponent referred briefly to some of the material provided in Sanders 3 and Ahyhankar, and the applicant addressed this material in their submissions. My understanding is that neither party disputes that the evidence should all be regarded under regulation 5.23. Nevertheless, this is not the determinative factor. As the Explanatory Statement stated in relation to former regulation 5.11, on which regulation 5.23 is based:

> "This power is discretionary – the patents legislation does not provide parties with a right to urge the Commissioner to make use of this power. As a result, the power in current regulation 5.11 cannot be used as a mechanism to delay opposition proceedings."

171. Regulation 5.23 sets out that:

> (1) For the purposes of deciding an opposition, the Commissioner may consult a document that:
>
> (a) is relevant to the opposition; and
>
> (b) has not been filed under this Chapter; and
>
> (c) is available in the Patent Office.

172. The Regulations do not mandate any procedure that the Commissioner must follow when new information is provided by a party. Rather, the Explanatory Statement says:

[128] OS at [140].

> "The Commissioner will be able to consider the document and then have the discretion to determine the most appropriate course of action in light of the information contained within the document."

173. It is not sufficient that the new information simply be of relevance to the issues in the opposition. The nature of the information must be such that it is *likely, if not certain, to change the outcome of the opposition in a significant way*.[129] Other matters may also be taken into account when considering whether the discretion should be exercised in favour of a party. These include the circumstances leading up to the evidence not being filed earlier and the balance of interests, including the public interest.[130] In the present case, I do not consider it necessary to consider these latter matters in any great detail. The key consideration is whether the information provided by the parties is crucial to my determination.

174. I have several concerns about the case put forward by the opponent.

175. Firstly, for anticipation there must be a clear and unmistakable disclosure of the features of the claim under consideration. The opponent's submissions for hearing refer to the tip of the nose being placed within the seal body and refer to the evidence of Mr Palkon suggesting that the seal should be placed over the user's nose. However, on the other hand, the evidence the opponent is seeking to introduce pursuant to regulation 5.23 relates to the seal positioned below the user's nose. My understanding is that the opponent does not resile from their position that the "correct" way of positioning the seal is with the tip of the nose inserted into the body of the seal. Nevertheless, they sought to rely on Abhyankar, Palkon 3, and Sanders 3 to confirm that, *"when worn in a normal manner"*, portions cover the sides of the nose.[131] This raises uncertainties as to what the case put forward by the opponent actually is, and whether the additional evidence is relevant to that case.

176. Secondly, the evidence provided by the opponent purports to show the position of the ComfortCurve™ *in use*. However, the photographs do not actually show the mask in use. The mask is manually held in place, not by headgear, as would be required during fitting and use. Mr Eaton stated that it is not possible to fit a mask without appropriate headgear since mechanical pushing and holding is not comparable to the mechanical force given by the elastic pulling force created by the headgear.[132]

177. In this regard, Ms Abhyankar stated that she held the mask against Ms Sanders face to approximate the pressure the headgear would have provided. However, Mr Eaton noted that the mask is held in different ways in different photographs.[133] He was also unable to ascertain whether the orientation in which the mask was held is different to when it was worn properly. The headgear used with the ComfortCurve™ was intended to be secured above the ears.[134] However, if the headgear were attached to the mask positioned as it was in the photographs, Mr Eaton considered it may sit below or on the user's ears.[135] It also seems to me that the characteristics of headgear and the way they hold the mask in place would vary from one type

---

[129] *Merial Limited v Bayer Intellectual Property GmbH* [2015] APO 16 at [24].
[130] *Reflex Instruments Asia Pacific Pty Ltd v Minnovare Limited* [2017] APO 8 at [49].
[131] OS at [141].
[132] Eaton 3 at [15] to [16].
[133] Eaton 3 at [16].
[134] Palkon 1 at [142] and Palkon 3 at [16]
[135] Eaton 3 at [17].

to another. No details were provided in relation to how the properties of the specific headgear used with the ComfortCurve™ were approximated when holding the mask manually.

178. Thirdly, the evidence sought to be introduced pursuant to regulation 5.23 is mainly concerned with whether or not the side portions of the ComfortCurve™ extend across the sides of the nose. Little detail was provided as to the other features of the claim. Admittedly, Ms Sanders stated that she felt the cushion touch the base and sides of her nose, though she does not explain what she means by these terms. In any case it is not readily apparent from the photographs the extent to which contact with the sides of the nose (as I have interpreted the term) occurs, and indeed whether *all* of the features of the claims are taken. The focus of the additional evidence is clearly on whether or not the mask extends across the sides of the nose. The case put forward based on the additional evidence would appear to require a mosaic of information already in evidence (relating to the mask being positioned *around* the nose) and the information that the opponent is seeking to have considered pursuant to regulation 5.23 (and relating to the mask being positioned *below* the nose) in order for there to be a disclosure of all of the features of the claims. Given the significant differences in the positioning of the mask in each case, I do not consider the evidence given in relation to the first necessarily extends to the second.

179. Finally, the gist of the opponent's submissions is that these photographs, taken some years after the priority date of the present applications and without actually showing the masks in ordinary use, should be accepted in preference to the information provided by the ComfortCurve™ manual. However, I consider that the instructions given in the manual provided with the product have significant evidentiary weight as to how the mask was fitted at the relevant time. The opponent has adduced no clear evidence that users, *at the relevant time*, fitted the mask in a manner that took all the essential features of the claims. Instead, two alternate arguments are being put forward without committing to the position set out in the evidence now requested under regulation 5.23. But in any case, it seems to me that if the evidence is not clear as to the correct placement of the ComfortCurve™ mask at the relevant time, then it could hardly be said that that the prior art provides clear and unmistakable directions to the present invention.

180. Given my concerns, and the deficiencies in the evidence adduced in relation to the fitting of the ComfortCurve™ at the relevant time, I do not consider that it would change the outcome of the opposition in any significant way. Therefore, I have not taken Abhyankar, Palkon 3, Sanders 3 and Eaton 3 into account in my determination.

181. The opponent also sought to rely on a device that they brought to the hearing. They submitted that the device was already in evidence, and that the applicant had had the opportunity to view it. At the hearing I declined the opponent's suggestion that the Commissioner make a direction or notice to introduce the device into evidence. In short, I consider the evidence already in the opposition consisted of photographs of the physical devices. The parties had filed written evidence based on those devices. However, no devices have ever been entered into evidence. To the extent that any submissions were required in relation to the physical product, then that information should have already been in evidence, and reliance on the physical device should therefore be unnecessary. If there was different information associated with the physical product, then a request should have been made earlier in proceedings together with details of the additional information.

182. Returning to the evidence in the proceedings, I am not satisfied that the present claims are anticipated by the Respironics ComfortCurve™ mask. None of the evidence provided in support of the opponent's submissions provides a clear and unmistakable disclosure of the

features of the present claims. In particular, even if I accept the central and side portions as identified by Mr Palkon, and the submission that the ComfortCurve™ is placed over, rather than under, the nose, I do not consider that all of the features of the present claims are disclosed. If the nose if placed within the hole, then the central portion of the seal does not appear to extend across the base of the nose, and the side portions do not extend from the edges of the central portion (that is from the base of the nose). Rather the placement of the nose within the hole would (presumably) result in the side portions extending from a point at the flank of the nose and above the base of the nose. Indeed, this arrangement would appear to result in the side portions, as identified by Mr Palkon, extending across the cheeks rather than the sides of the nose. But in any case, the specific placement of the mask on the user's face, and the specific features defined in the present claims, cannot be gleaned from the evidence provided.

183. The claims of all of the applications are therefore novel in view of the information relating to the prior use of the ComfortCurve™ mask seal given in U2.

Document D3 (Handke)

184. Handke describes a miniature nasal mask which is said to include

> "a soft pliable perimeter cushion that contacts a facial area limited essentially to a vertical extent between the tip and lateral flank portions of the user's nose adjacent the nares and the user's upper lip, and a lateral extent comprising only an area between the cheek portions of the face immediately adjacent to the base of the nose and the upper lip."[136]

185. Handke goes on to state that the "balloon seal" of the mask "includes a thin, textured, elastomeric membrane which forms sealing contact" with the portion of the user's face identified above. The high degree of seal flexibility is said to maintain a high integrity surface seal with even a very small positive pressure within the mask, and with only minimal strapping or retention force.[137]

186. A representation of the mask seal is shown below.[138] Gas is provided via port 54 into a cavity 56. The user breathes gas supplied to the cavity via an opening 60 formed in flap seal portion 58 and located to confront the nares of the user.[139]

[136] D3 at column 1, lines 53 to 58.
[137] D3 at column 2, lines 19 to 26.
[138] D3, Figure 3.
[139] D3, column 3, line 66 to column 4, line 5.

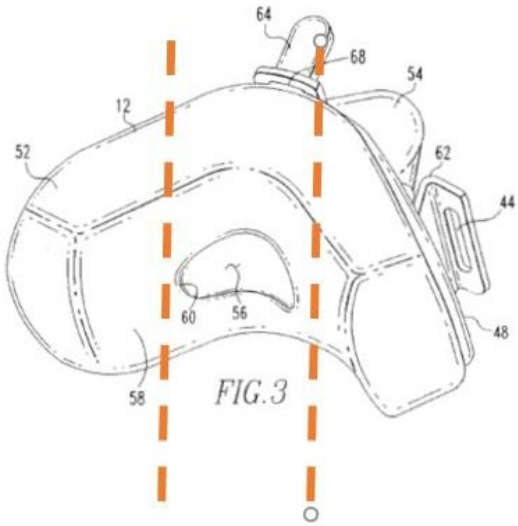
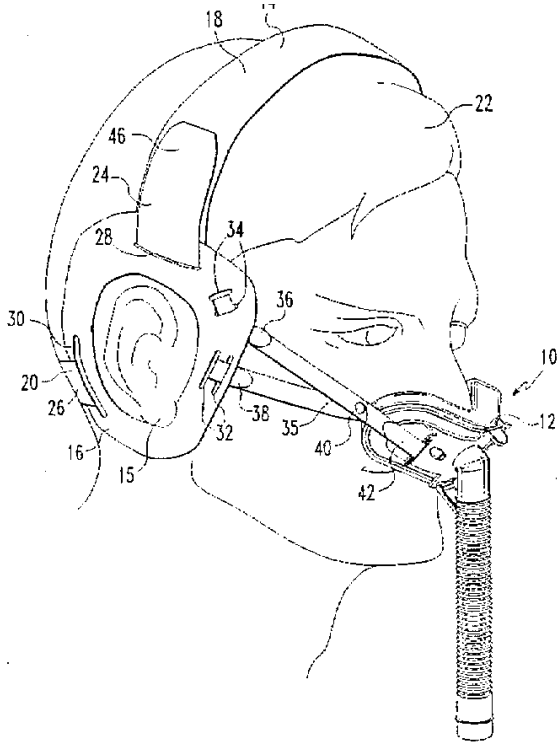


FIG.3

187. The mask has a generally V-shaped configuration which is said to open or diverge in an anterior to posterior direction which conforms to the anatomical structure of the user's nose and upper lip.[140] The flap seal portion 58 is said to be a very thin section, flappable, flexible seal portion which is capable of conforming precisely to variations in the user's face in the contact area under only minimal inflation pressure.[141] The dotted orange lines show the boundaries between the central and side portions as identified by Mr Palkon.[142]

188. In use, the mask is said to be placed in position as shown in Figure 1 below.



[140] D3 at column 4, lines 17 to 25.
[141] D3 at column 5, lines 25 to 32.
[142] Exhibit DJP-23, integer 1.4.

189. Figure 9 (shown below) shows the mask seal contact area, which is described as follows:

> "contact by an outer surface 102 of the perimeter portion 100 of cushion member 50, is limited to the facial area essentially defined as a vertical extent having the tip 120 and immediately adjacent lateral flanks 122 of the user's nose adjacent to the nares 124 as its upper extremity, and the user's upper lip 126 as its lower extremity, and a lateral extent having the cheek portions 128 of the user's face laterally adjacent to both the base 130 of the nose and the upper lip 126 as its lateral extremities."[143]

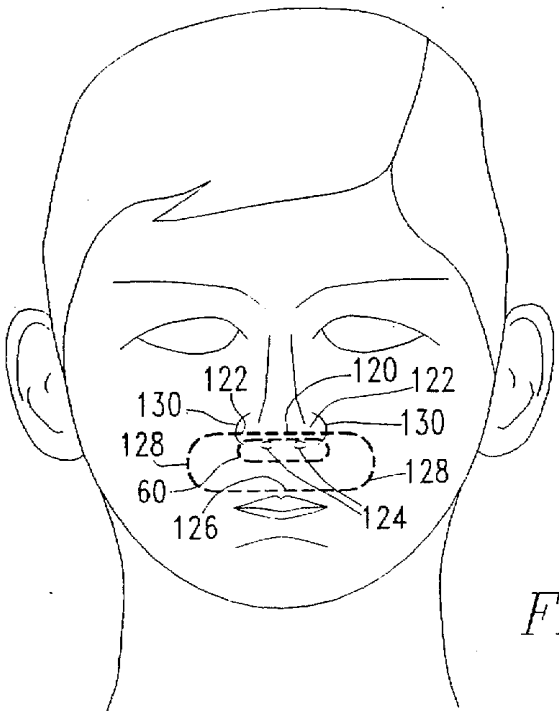


FIG. 9

190. The key point in dispute was the position of the mask with respect to the sides of the nose. Mr Eaton understood from the above description and Figure 9 that the seal contact surfaces are those visible from below the nose.[144] Mr Eaton also noted that the Handke mask was intended to be a miniature mask,[145] and went on to note the stated advantages of the mask arrangement stated:

> "Further, the low posture of the mask, **residing essentially at or below the lowermost extent of the user's nose**, reduces the potential for irritating eye leaks and does not interfere with the user's normal field of vision"[146] [emphasis added].

191. At the hearing the applicant also argued that the V-shape of the Handke product meant that the seal extended away from, rather than across the sides of the nose, and if there was any contact of the seal with the sides then this was a *de minimis* amount that would not deprive the claims of novelty.[147]

---

[143] D3, column 5, lines 43 to 52.
[144] AS at [98], citing Eaton at [401].
[145] Eaton 1 at [406].
[146] Eaton 1 at [407], citing D3 at column 2, lines 5 to 9.
[147] *Old Digger Pty Ltd v Azuko Pty Ltd* [2000] FCA 676; 51 IPR 43 at [171].

192. The opponent submitted at the hearing that the nose was placed inside of the hole in the mask seal. They also referred to the manner in which the mask was positioned when worn, as indicated by Figure 1. In response to the applicant's submissions that there is no teaching in D3 to anything other than limit the coverage to the specific region shown in Figure 9, the opponent submitted that the alternative embodiments shown in Figures 10 to 12 show broader coverage of the nose. These embodiments utilise a nasal cannula in place of the hole. The opponent referred in particular to Figure 10, as shown below.

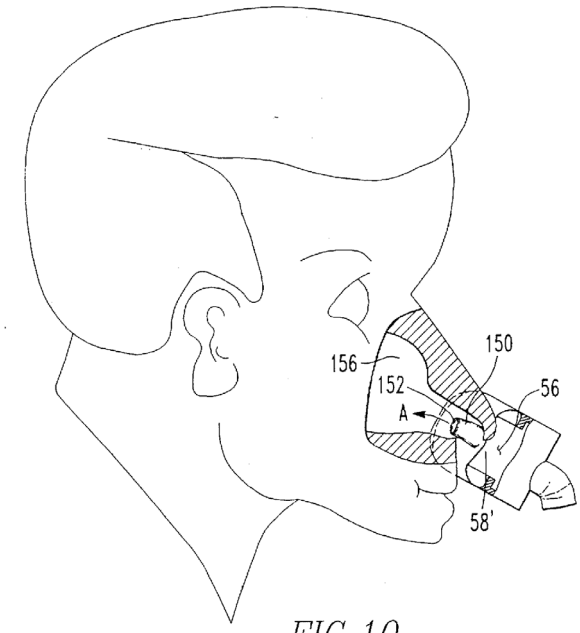


FIG. 10

193. On balance, I do not find the opponent's submissions to be persuasive. Looking first at the issue of where the mask is positioned on the user's nose, the key difference between the parties appears to lie in whether mask sits around the user's nose, or whether the user's nose is placed on top of the seal flap surface. At the hearing the opponent argued that the nose must be placed within the hole, since the alternative would give a poor seal and result in air leaks. However, placement of the mask below the nose appears to be consistent with that generally used for nasal pillows masks, where the mask cushion sits below the nose and seals around the surfaces surrounding the nostrils.[148] I therefore do not find this submission determinative of how the seal is positioned. The opponent also referred to Figure 1 in support of their submissions that the user's nose is placed within the seal body. However, Figure 1 does not show the seal engages with the nose of the user when it is positioned in the mask body, and indeed suggests that the mask is so big as to cover the user's mouth. I do not consider that this figure supports the assertion that the nose of the user is placed within the hole in the seal.

194. Similarly, the parties each relied on Figures 9 and 10 which provide a general illustration of the positioning of the respective positioning of the pillow and cannula seals. However, in my opinion neither of these could be considered anatomically accurate, and I consider there are limits to the reliance that can be placed on these basic technical drawings as being representative of how the mask is sized and fitted in practice. In the case of Figure 10, the seal does not appear to be positioned in the manner required of the invention. The specific positioning of the seal against the sides of the nose is not shown, nor do I consider it could be reasonably inferred from the figure. Moreover, the cannula-style seals are fundamentally different to the flap seals

[148] Palkon 1 at [93] and Eaton 1 at [76].

shown, for example, in Figures 1 and 3, so I do not consider that the positioning of the mask in Figure 10 necessarily can be extrapolated to the nasal pillows-style of mask, which I understand the mask of Figure 3 to represent.

195. Ultimately, I consider the body of the specification provides the most accurate description of the invention. To that end, the mask is meant to be positioned at or below the lowermost extent of the user's nose. I understand this to correspond to the base of the nose. The mask is said to contact only the area between the tip of the nose and the immediately adjacent *lateral flanks* adjacent to the nares. Mr Palkon stated that he was not familiar with the term, but, based on the ordinary meaning of the terms "lateral" and "flanks", he considered "lateral flanks" meant "a part of the nose that is positioned to the side of the nose". He identified these as the "flared regions at the sides of the nostrils" (which I understand to be the ala on each side of the nose). Mr Palkon referred to the numbering given in Figure 9, and particularly the labelling of the lateral flanks as 122. He highlighted in blue the area he considered to be the lateral flanks in Figure 9, which for convenience is given below.

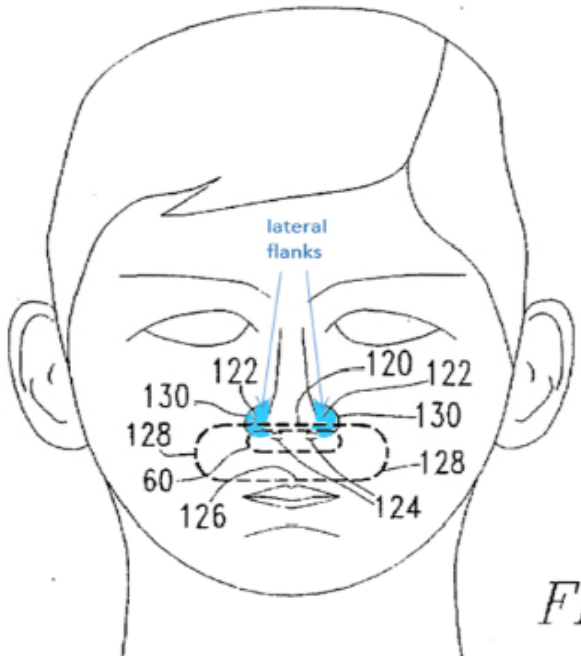


FIG. 9

196. As an initial observation, I have some concerns with the labels given in Figure 9 of Handke since 122 is said to refer to the lateral flanks of the nose but appears to be directed towards the front of the nose and towards the upper dotted line representing the upper limit of the seal. Moreover, 130 is said to represent the base of the nose but the label in Figure 9 indicates this to be well above the base of the nose, and at the rear of the nose. It appears to me that these labels may have been reversed.

197. That aside, taking the approach of giving the term "lateral flanks" an ordinary meaning, I do not consider that the region identified extends to the surfaces of the sides of the nose as required by the present claims. Even if I accept Mr Palkon's interpretation of the lateral flanks referring to the ala pads on each side of the nose and extending to the alar rim on the base of the nose, the term is further characterised as being adjacent to the nares. In the region identified by Mr Palkon, I consider this would correspond to the outside rim of the base of the nose (that is the area immediately around the nares on the base of the nose). That is also consistent with the mask seal contact area represented by the dotted lines in Figure 9. Notably, the area represented by the hole in the seal sits adjacent to, and below the nares. If the mask seal extends to the

surfaces of the sides of the nose, which I do not consider to be clearly disclosed by the detailed description of the mask or any of the figures, this would likely be to a *de minimis* degree. However, I do not consider that Handke provides clear and unmistakable directions to even this level of coverage.

198. In short, the present claims are novel in view of D3 (Handke).

U3 – the Respironics Monarch Mini

199. The Monarch Mini and the mask described in D3 (Handke) are similar, and the submissions for U3 were therefore much the same as D3. Thus, the opponent submitted that the mask is not worn below the nose, referring to Figure 1 of the user manual for the Monarch Mini,[149] which appears to be the same as Figure 1 of D3. The applicant similarly sought to distinguish the present claims on the basis that U3 does not disclose the side portions of the mask as defined by the present claims.

200. The SGP referred to the public display, sale, offer for sale and use of the Monarch Mini. The product and the associated user guide were used by the opponent to infer how the product was used. The applicant pointed out that this would appear to constitute a combination of information provided through doing an act and information provided by a document, which is impermissible under section 7(1)(b). I do not agree with this submission. It would seem to me that the sale or supply of the product together with the manual would constitute a single act, similar to the single act of displaying photographs and explaining the features of the photographs.[150] The combination of this act with the subsequent act of using the machine would seem to be consistent with section 7(1)(b) in that the relationship between these acts is such that a person skilled in the art would treat them as a single source of information.

201. Ultimately, whether or not the separate pieces of information may be regarded as a single source for the novelty determination with respect to U2 does not lead to a result that is different from my determination for D3. None of the photographs or diagrams provides any detail of where the nose fits in the mask or the characteristics of the mask when inflated. I am therefore unable to determine whether the mask sits above or below the user's nose, or whether the sides of the mask extend across the sides of the nose and conform under internal pressure to the sides of the surfaces of the sides of the nose. The opponent argued that the applicant had not provided evidence that would show that the mask could be worn below the nose and achieve an effective seal. However, it is the opponent who bears the onus in the opposition, and for the purposes of prior use, this includes establishing that the mask would have been (rather than could have been) worn in the way they assert. Regardless of how the mask sits, the evidence provided in support of this ground provides insufficient detail for me to conclude that all of the features of the present claims are disclosed.

202. I therefore consider that the present claims are novel in view of U2 (the Monarch Mini).

Document D4 (Starr)

203. Starr describes a flexible mask seal comprising a recessed section that substantially conforms to the shape of the user's nose. Two types of mask are described: a full face mask (referred to in D4 as feature **18**), and a nasal mask which is shown below in Figure 6.

---

[149] Exhibit MC-5.
[150] *Aspirating IP Limited v Vision Systems Limited* [2010] FCA 1061 at [287] to [288].

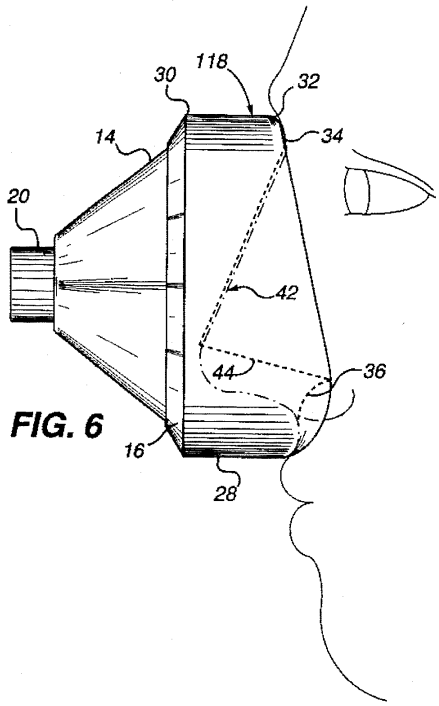


FIG. 6

204. The features of the mask are described as follows:

> "…facial seal **118** is a nasal or half mask, the flap seal **34** of which establishes a seal surface **36** whose contour closely approximates the surface contour of a user's facial structure in the area of the bridge of the nose and the adjacent cheek structure. Situated opposite seal surface **36**, of course, is gas flow bearing surface **38** as described above. Thus, unlike seal **18** which also accommodates the user's chin structure, seal **118** instead accommodates the area intermediate the nose and upper lip, and the interventing (sic) areas contiguous to these. In all other respects facial seal **118** is structurally, functionally and conceptually similar to facial seal **18**."[151]

205. Notably, the user's nose sits within the recess in the mask and the mask conforms to the surfaces in the area of the bridge of the nose and adjacent cheeks. As indicated by the dotted line **44** shown in Figure 6, the side flaps of the mask lie across the sides of the nose. There is no central portion on the inner facing wall that extends across the base of the nose, and therefore the side portions do not extend from such a central portion and contact the sides of the nose.

206. In short, I do not consider that the claims lack novelty in view of D4.

Conclusion on novelty

207. None of the claims of the applications lack novelty in view of the cited prior art. The opposition is unsuccessful on the ground of novelty.

Inventive step

208. Section 7(2) of the Act sets out that an invention is taken to involve an inventive step unless it would have been obvious to the person skilled in the art in the light of the common general

[151] D4 at column 7, lines 28 to 39.

knowledge, either considered alone or together with information of the kind set out in section 7(3) of the Act.

209. Nicholas J recently provided a succinct statement of principles relevant to assessing inventive step in *Hood v Bush Pharmacy Pty Ltd*:

> "Section 7(2) of the Act uses the word 'obvious' in the course of describing what must be established before an invention can be held not involve an inventive step. Something may be 'obvious' in light of the common general knowledge, or the common general knowledge coupled with the relevant s 7(3) information, if it is 'plain or open to the eye or mind, something which is perfectly evident to the person thinking on the subject' or something which 'would at once occur to anyone acquainted with the subject and desirous of accomplishing the end'.
>
> An invention may also be obvious in light of the common general knowledge if the person skilled in the art faced with the same problem as the inventor would have taken as a matter of routine whatever steps might have led from the prior art to the invention, whether they be the steps of the inventor or not or (using the language of the 'modified Cripps question') if the person skilled in the art would be directly led as a matter of course to take such steps in the expectation that doing so might well produce a useful or better alternative to the prior art. However, a claimed invention is not obvious merely because the person skilled in the art would consider that it was 'worthwhile to try'."[152]

210. The modified Cripps question requires that there be a reasonable expectation of success. This is explicit in the expectation that an approach "might well" succeed, and implicit in the characterisation of steps as those to be taken as a matter of routine.[153] However, success need not be guaranteed: "the relevant test is not knowing that steps will or would or even may well work, but merely expecting that the steps may well work."[154] Further, it is possible that the skilled person might be directly led to try more than one alternative expecting that each may well produce a useful or desired result.[155]

Inventive step in view of common general knowledge alone

211. The opponent forwarded two alternative cases under this ground. The first was based on the premise that the applications do not disclose what is said to be the invention in the sense of disclosing:

    a. Any useful differences from, or advances upon, the prior art;

    b. The solution to any particular problem; or

    c. Any difficulty that has been overcome.[156]

---

[152] [2020] FCA 1686 at [116]-[117] (citations omitted).
[153] *Generic Health Pty Ltd v Bayer Pharma Aktiengesellschaft* [2014] FCAFC 73; 314 ALR 91 at [71].
[154] *Nichia Corporation v Arrow Electronics Australia Pty Ltd* [2019] FCAFC 2 at [99].
[155] *Mylan Health Pty Ltd (formerly BGP Products Pty Ltd) v Sun Pharma ANZ Pty Ltd (formerly Ranbaxy Australia Pty Ltd* [2019] FCA 28 at [192], *Nichia Corporation v Arrow Electronics Australia Pty Ltd* [2019] FCAFC 2 at [91]-[93].
[156] OS at [171].

212. They submitted that:

> "Where the patent applicant has not itself been able to identify in each Opposed Application what is said to comprise any relevant advance, this points away from there being an inventive step. Such a conclusion can also be more readily reached where the patent applicant's expert has not identified any relevant advance – something 'beyond the skill of the calling' – following their review of the applications (as is the case in this proceeding)."[157]

213. The opponent referred me to *Konami v Aristocrat*, where the Full Court considered the validity of a patent that did not assert any particular problem had been solved. In upholding the trial judge's finding as to lack of inventive step, the Full Court stated that:

> "The 847 patent involved a number of features in combination in a poker machine game. The combination of features was not said to solve any particular problem. I can discern in the combinations no problem solved or frontier crossed. There was, in that circumstance, nothing remotely inventive about the 847 Patent…"[158]

214. The opponent argued that each of the claims of the opposed applications lacks inventive step because none of the claimed subject matter overcomes any difficulty, crosses any barrier or does anything that has been suggested to be beyond the skill of the calling. There is nothing in the dependent claims that is other than routine, that addresses any known problem in the art, or makes any inventive contribution. Inflatable nasal seals were well known before the priority date, and no relevant difference or improvement upon such masks is taught in the applications.[159]

215. The second line of argument under this ground was based, pursuant to the applications identifying no specific problem to be solved, on the premise that the invention merely relates to the production of an alternative nasal mask for use as part of CPAP or similar therapy.[160] To this end the opponent submitted that each of the features of the claim were "well known" or routine variations.[161] They argued that there was no suggestion that any of the features, considered separately or in combination, involves some relevant advance in the field or addresses some particular problem.[162] Mr Palkon stated that the generality of claim 1 was such as to describe all nasal masks that he was familiar with.[163]

216. The applicant considered that the opponent's submissions misplaced the burden that the opponent bears in establishing that the claims lack inventive step. They argued that this does not involve an assessment of whether there is an advance disclosed in the specification, or what Mr Eaton says about the matter. They observed that the opponent advanced very little direct evidence on the question of inventive step. They also noted that Mr Palkon had been asked to first provide general evidence on CPAP therapy, masks, headgear and seals that he considered common general knowledge, and then his opinion about the applications and his construction of various terms. Finally, he was shown the prior art and asked to indicate whether the prior

---

[157] OS at [172].
[158] *Konami Australia Pty Ltd v Aristocrat Technologies Australia Pty Ltd* (2016) 119 IPR 402; [2016] FCAFC 103 at [102].
[159] OS at [174] to [175].
[160] OS at [176].
[161] OS at [181].
[162] OS at [182] to [183].
[163] OS at [184].

art disclosed each of the integers of the present claims. In doing so, he made observations about whether it would have been obvious to modify certain of those integers. The applicant submitted that he did not explain why the skilled person would have been motivated to make such changes, or provide evidence as to why they would be motivated to combine those features. They noted that his comments were also made having been given the invention.[164]

217. I share the concerns of the applicant in this regard. I also note that Mr Palkon could not determine the meanings of several terms used in the claims. This raises the question that, if Mr Palkon has been unable to determine the meaning of the terms and, therefore, what the invention is, is he in a position to determine whether that invention is obvious? For example, the opponent submitted at hearing that:

> "It was routine for nasal masks to extend across at least part of the sides of the nose. It would be difficult for the nasal seal to avoid touching the sides of the nose. There is no suggestion to the contrary in the Opposed Applications, or by Mr Eaton."[165]

218. The difficulty I have with the opponent's submissions on this point, and indeed their evidence in general, is that Mr Palkon stated that it was unclear what was meant by the term "sides of the nose" as used in the claims. He proffered two alternative meanings but did not state which of these was the meaning that he would ordinarily understand the term to mean, or indeed whether there was some other meaning, and which meaning he applied to the consideration in hand.

219. Notwithstanding the lack of any clear position on this point, the opponent referred to Mr Palkon's statement that nasal pillows touch the base and sides of the nose,[166] and asserted that Mr Eaton generally agreed with this statement.[167] I do not understand this to be the case. Mr Eaton stated that nasal pillows typically sealed *"around the surfaces surrounding the nostrils"*. This is consistent with one of the alternatives suggested by Mr Palkon, and would suggest that the opponent's case is predicated on the sides of the nose being the area on the base of the nose between the nostrils and the ala. That being the case, it not surprising that Mr Palkon stated that the generality of claim 1 was such as to describe all nasal masks that he was familiar with.[168] It is undisputed that nasal pillows masks sit below the nose and contact the base of the nose, including the area around the nostrils. However, I have construed the sides of the nose as being located above the "rise" at the edges of the base of the nose when looked at from below. I therefore do not consider the opponent's submissions, which appear directed to the area surrounding the nostrils on the base of the nose rather than the sides of the nose, to be of much assistance in this regard.

220. The key issue in my mind is what the common general knowledge establishes was routine in the art in relation to masks of the present type. I am satisfied that several different types of nasal mask were common general knowledge: nasal masks that covered the user's nose, nasal pillows masks that sat below the user's nose, and cannula-type masks. I am also satisfied that inflatable nasal seals were known in the art, particularly in the case of full nasal masks comprising inflatable (or pressure-activated) cushions. Neither expert discussed inflatable or pressure-activated nasal pillow masks in great detail but I am satisfied that the evidence is sufficient to show that such masks were common general knowledge in the art. Finally, it was common to include stabilising features such as cheek and/or forehead supports. Mr Eaton stated

---

[164] AS at [178].
[165] OS at [181], integer 1.6.
[166] Palkon 1 at [93].
[167] OS, footnote 178.
[168] OS at [184], citing Palkon 1 at [246].

that the seal itself could include support features and contribute to overall stability,[169] and provided an example where a gel cushion support was interfaced with a thin and compliant silicone flap which contacted and sealed to the user's face. However, this was apparently an uncommon approach to mask design.[170]

221. When first given the present application(s), Mr Palkon stated that the reference in the Detailed Description to an inflatable seal and the use of nasal locators describes a *"nasal pillows mask with a pressure activated seal that wraps around the patient's nose (i.e. it is not simply underneath the nose)"*.[171] This suggests to me that side portions which wrap around the nose are not typical of nasal pillows masks. Moreover, such a configuration would not appear to clearly fall within any of the "categories" of masks identified by the experts. In this regard, Mr Eaton stated that:

> "A skilled person would understand these different types of CPAP interfaces as existing on a spectrum rather than in clearly defined and separate categories. The parameters of these terms are not definitive nor fixed, and I recall several 'hybrid' masks available on the market and/or patented at the Priority Date which do not fall squarely into a single category of CPAP interface. This is especially so with respect to the 'nasal pillows' and 'cannula-style' distinction, as the difference between these interfaces can be as little as the degree of extension of the seal into the nares, with cannula-style interfaces typically extending further into the nares and therefore feeling more intrusive."[172]

222. Mr Eaton went on to state that, within these broad and overlapping categories, there were "copious" options for the seal design. These included the extent, degree and location of facial contact with the seal, overall geometry of the seal and the configuration of specific components and material properties. There are apparently numerous trade-offs involved in each option.[173] Mr Eaton recalled that full nasal masks were the most prevalent configuration used. These had the advantage of having reliable and stable sealing surfaces, but greater effort and complexity was required to design interfaces that avoided the sensitive nasal bridge area.[174] There was also a push for interfaces that cover less of the user's face, and were smaller, sleeker, and less obtrusive. This was a key driver in the trend towards nasal pillows in the mid- to late-2000s.[175]

223. Nasal pillows apparently have the advantages that they are lighter, less visually intrusive as they sit below the user's nose, and avoid the nasal bridge, which helps avoid discomfort due to pressure, skin irritation and the risk of leaks into the eyes. However, nasal pillows are less stable than full nasal or full-face masks because they contact less of the user's face. They are therefore more prone to leaks, particularly with users who move a lot during sleep.[176] At the hearing, the applicant submitted that inflation of the seal against the surfaces of the sides of the nose and the face provides for greater stability of the seal against movement and leakage, allowing for less intrusive headgear and reducing the need for other stabilising attachments. In this regard they highlighted the following discussion of one of the preferred embodiments in the specification:

---

[169] Eaton 1 at [95].
[170] Eaton 1 at [96].
[171] Palkon 1 at [167].
[172] Eaton 1 at [79].
[173] Eaton 1 at [81].
[174] Eaton 1 at [84].
[175] Eaton 1 at [85]. See also Palkon 1 at [51].
[176] Eaton 1 at [86].

> "In use, the supple interior wall portions above, below and to each side of the nasal locators are inflated by pressure inside the seal (from the flow of gases supplied to the patient interface) to press against the skin of the wearer and conform to the contours of the outside surfaces of the nose of the wearer and to the surfaces of the lower face of the nose of the wearer and to the surfaces of the upper lip of the wearer immediately below the nose. Movement of the mask body does not break this seal, as the supple perimeter or periphery of the seal allows the mask body to move in the direction of movement to at least a small extent. The supple perimeter de-couples the position of the nostril locators from the position of the mask body, allowing the mask body to displace both laterally and vertically (relative to axes of the patient's face). The side portions 411 engage the sides of the patient's nose, and form some additional seal against them and support the location of the mask."[177]

224. On balance I am satisfied that the combination of features defined in the present claims is not obvious in view of the common general knowledge alone. In particular, the base of the user's nose sits on a central surface of the seal in a manner akin to a nasal pillows mask, but as indicated in the last sentence of the passage above, the side portions seal against the outer surfaces of the sides of the nose to support (and thereby stabilise) the seal. There is nothing in the evidence to suggest that this type of configuration in (inflatable) nasal masks was common general knowledge in the art at the time. To the contrary, the evidence suggests that it was common to avoid designing a mask that would seal or inflate around the outsides of the nose because it could give a pinching or blocking sensation, and that the focus was therefore on masks that had a low profile which sat below the user's nose.[178] .

225. I therefore consider the opponent has not made out this ground of opposition.

Obviousness in view of the common general knowledge and each prior art document

226. The opponent's submissions on this ground of opposition were relatively brief:

> "(a) Each of the prior art examples that ResMed relies on is itself an example of a useful inflatable nasal mask.
>
> (b) To the extent that there are differences from what is claimed in each of the claims, those differences are routine, and cannot contribute an inventive step. They involve a routine variation only.
>
> (c) For many of the integers, no question of being 'directly led' to adopt the relevant integer arises, precisely because the integer is routine or unimportant. For that same reason, the inclusion of such an integer or integers into the claim cannot result in the claim being to patentable subject matter because what has been specified is merely an obvious variation, and not something that involves a contribution beyond the calling capable of meriting patent protection."[179]

227. The applicant noted that the opponent's case is advanced at a very high level of generality without any evidence cited in support of their position. They went on to submit that:

> "This does not address the fundamental question of whether each of the claims is inventive in accordance with the well established principles on inventive step. It is not supported by

[177] Specification at page 18, lines 21 to 31.
[178] Eaton 1 at [84].
[179] OS at [204].

> the evidence; is an impermissible consideration of the claimed invention integer by integer, rather than assessing whether the whole of the claimed invention would have been obvious; fails to articulate any reason why the skilled person would be motivated to modify the prior art to include the claimed feature, and reject other possible alternatives; does not establish that any such modification would have been incorporated as a matter of routine; and impermissibly seeks to disregard 'many of the integers' on the purported basis that the integer is 'routine or unimportant', without any evidence or proposition of law to support that approach."[180]

228. I agree with the applicant on this point. The opponent's boilerplate submissions are so vague as to preclude any identification of the case to be answered. The opposition is unsuccessful on this ground.

Clarity

229. Section 40(3) requires that the claims must be clear. A claim will lack clarity if a third party would be unable to ascertain whether an act would fall within the scope of the claim.[181] Some of these issues relate more generally to the construction given to the claims, which I have covered above. As noted in that discussion, many of the issues raised by the opponent result from the imprecision of some of the terms. This, in itself, is not fatal to the validity of a claim.[182] As noted by the applicant:

> "The use of functional language in and of itself does not give rise to any clarity complaint. Thus it is common for patent claims to use such terms. The question is whether, applying usual cannons (sic) of construction, the functional terms provide a workable standard. It is important when construing a functional term to not consider it in isolation but to consider it in the context of the claim as a whole (including where relevant, other claims and, ultimately, the body of the specification)."[183]

230. The opponent made submissions on the clarity of the following terms.

Side portions and central portions

231. I have previously discussed and given a meaning to these terms as part of my claim construction. I do not consider that the claims would lack clarity on that basis.

232. The opponent also referred to statements by Mr Eaton suggesting that whether a mask has side portions will depend on the size of the user's (or manikin's) face. They argued that if this evidence was accepted then the assessment of whether the product falls within the claim or not will depend upon an unfixed reference point (being the variable features of a user's face), and on subjective views as to whether a mask is the correct size for a particular person or not.[184] The claims would be unclear as a result.

233. The applicant submitted that neither of these propositions bear scrutiny. All inflatable seal masks come with instructions as to their proper sizing and fitting, and it is a relatively simple

---

[180] AS at [203].
[181] *Monsanto Co v Commissioner of Patents* (1974) 48 ALJR 59.
[182] *Flexible Steel Lacing Co v Beltreco Ltd* [2000] FCA 890; (2000) 49 IPR 331 at [81].
[183] AS at [233].
[184] OS at [212] referring to Eaton 1 at [508].

matter to determine whether a mask, *which is properly sized and fitted for a face*, will have the claimed features of side portions and a central portion.[185]

234. To some extent, the opponent's submissions conflate the separate and different considerations for novelty and clarity. The opponent relied on more recent photographs of a mask in position on a mannikin in order to establish that the use of the Sullivan bubble mask before the priority date anticipated the present claims. This requires that the prior use disclose all the features of the claim and provide clear and unmistakable directions to the invention. I consider it reasonable as part of that exercise to consider whether the mask has been properly sized and fitted in the manner that it *would have been*, rather than *could have been*, at the relevant time, in order to determine whether the features of the claims have been disclosed. For the determination of clarity, the consideration is whether another party could ascertain whether an act would fall within the scope of the claim. As discussed previously, the claims use imprecise terms, but I am satisfied that, given the disclosure in the specification and my construction of the terminology, the skilled person would be able to give the terms in the claim a practical meaning, including where users have different facial geometry.

235. In short, I do not consider the claims of all of the applications lack clarity on this basis.

Outer-wall, inward-facing wall, and perimeter portion/peripheral portion

236. The opponent noted that claim 1 refers to *sides* of the seal and claims 25 and 26 refer to *surfaces* of the side and central portions, but claims 15 to 17, 23 and 24 refer to *walls* and a *perimeter portion*. They questioned how, if the central portion extends across the user's nose, does that part of the seal have outward and inward-facing walls and a perimeter portion?[186]

237. I do not consider that the claims lack clarity when these terms are read in the context of the claims. In particular, as noted by the applicant, claim 15 is dependent on claim 10, which is in turn dependent on claim 1. Claim 10 makes it clear that the central portion has an exterior side (and logically, an interior side). The exterior side has an opening for gases to pass to and from the interior of the seal. I consider it a common-sense interpretation that the exterior side of the central portion is the region of the external facing side of the mask corresponding to the patient-facing area defined by the base of the nose and the side portions, and in which the user's nose sits when the mask is in use.

238. Claim 15 then further characterises the central portion as having an outer facing wall, inward-facing wall, and a perimeter portion. I do not share the concerns of the opponent in relation to these terms. A wall generally refers to the structure that encloses a space, which in this case is the structure that forms the inflatable seal. The inward-facing wall of the seal is clearly the wall of the seal on the patient (or inward)-facing side of the mask. The outer-facing wall is the wall of the seal on the exterior side of the seal. There is no clarity issue in this regard.

239. The claims refer to the perimeter portion and peripheral portion which I understand to be used synonymously. As discussed previously, I consider that this refers to a region situated between the outer- and inward-facing walls of the mask. Mr Palkon appears to have had difficulty with the meaning of this term because he understood the term "perimeter" to refer to a boundary line

[185] AS at [240].
[186] OS at [213] to [215].

rather than an area.[187] However, the term used in the claims is "perimeter portion". In this context I am satisfied that the term refers to an area rather than simply a line.

240. In summary, the terms "outer-wall", "inward-facing wall", and "perimeter wall" are clear in meaning in the context in which they are used in the claims.

Top edge, end edge and lower edge

241. The opponent submitted that claim 16 of '838 defines that the peripheral edge portion extends around a top edge, end edge and lower edge, but does not state what these edges refer to. I do not have a concern with this definition. The claim is clearly defining that the peripheral portion that joins the inner face portion and the outward face portions extends around the top, end(s) and lower parts of the mask. The opposition fails on this point.

Substantially parallel and substantially normal

242. Claim 20 of '628 defines that the side portions of the seal are substantially parallel to each other and substantially normal to the central portion of the seal. Claim 21 further characterises the seal as having a parabolic, half elliptical, half oval or U-shaped overall plan form.

243. The opponent noted that Mr Palkon considered that the term "substantially" unclear and submitted that there is no practical benchmark against which such an assessment may be made.[188] The opponent submitted that even looking at the figures, it is difficult to understand how the side portions could be said to be *substantially normal* to the *central portion*. The description at page 20 instead refers to them as being *substantially perpendicular* to a *width dimension*. I do not consider these to differ significantly in meaning. The reference in the first instance is to the central portion as a whole, rather than say, a point on the central portion. I consider a common-sense approach would mean that the normal would be relative to the plane in which the central portion lies. This is essentially the width dimension.

244. The applicant submitted that the context in which the words are used is important, and resort may be had to the specification. They argued that the term "substantially" simply means the side portions need not be perfectly parallel or normal to their reference line. The specification uses the term consistently and provides the following context:

> "The overall plan form of the seal, as illustrated in Figure 7A, could be considered parabolic, half elliptical, half oval or U-shaped. Viewed generally, the central portion of the seal defines the width of the seal, with the side portions of the seal extending away from the lateral ends of the central portion in a direction substantially parallel with each other and substantially perpendicular to this width dimension."[189]

245. On balance, I do not find the opponent's submissions persuasive. The term "substantially" in the context in which it is used, and as illustrated by the different specific embodiments defined in claim 21, provides for a degree of variation from the perpendicular extension of the side portions. Moreover, the claims include functional limitations that also provide further context for the interpretation of the terms. The opponent's case on this point is unsuccessful.

Regions much stiffer… extending into the side portions

---

[187] Palkon 1 at [302].
[188] OS at [218].
[189] Specification at page 20, lines 19 to 23.

246. Claim 1 of each of applications '628, '840 and '843 define that an exterior side of the mask seal include regions that are much stiffer than the supple interior side, and that those regions extend into the side portions of the seal.

247. Mr Palkon also considered the term "much stiffer" was not clear since the claim does not provide the degree of difference for a material to be much stiffer (rather than just stiffer) than the supple part of the seal. He went on to state that it was common in masks for part of the seal to be made stiffer than the part that contacts the face, as the stiffer parts provide structure while the softer sections deform under pressure and form the seal. However, Mr Palkon noted that the claim does not simply require the section to be stiffer, but *much* stiffer.[190]

248. On the other hand, Mr Eaton stated that the term "much stiffer" means that there is a significant increase in the stiffness as compared to the interior surface, and that a skilled person would readily understand what was meant in the context of a mask seal.[191] He went on to state that a skilled person would readily understand, through ordinary testing and evaluation, how to change the thickness and shape of a material in response to variations in durometer to achieve the desired suppleness of some regions of the seal and relative stiffness of others.[192]

249. I agree with the opponent's submissions that the term "much stiffer" is a relative term and the degree of difference is not set out in the claims. Nevertheless, as noted by Mr Palkon, stiff regions were commonly incorporated in face masks to strengthen certain parts of the mask. Mr Palkon did not quantify how much stiffer these types of strengthening regions were in the prior art masks, though presumably a certain level of stiffness would be required to achieve the desired outcomes. A similar consideration would be applicable here. The stiffened areas would be sufficiently stiffened to achieve the desired level of structural integrity, and not so stiff to make the material unsuitable for use as a face mask. Thus, for example the specification states that:

> "A substantial extent of the seal body or envelope is supple. A region adjacent and including the nasal locators and a region adjacent and including the inlet opening are much stiffer. These areas hold the overall shape of the seal and can be of any suitable stiffness. As such they may be formed of a stiffer material, or formed thicker in the same material as the rest of the envelope".[193]

250. Similarly, the "regions much stiffer than the supple interior side resist outward flexing of the side portions of the seal when the seal is inflated under pressure".[194] Despite the inherent imprecision in the meaning of the term "much stiffer", I consider that the skilled person would understand that the material is sufficiently stiff to achieve desired structural purposes. The opposition is unsuccessful on this point.

Support

251. In addition to the requirement that the claims are clear, Section 40(3) requires that the claims are supported. At the heart of this consideration is the principle that the "extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art

---

[190] Palkon 1 at [231].
[191] Eaton 1 at [174].
[192] Eaton 1 at [177].
[193] Specification at page 14, lines 19 to 22.
[194] Specification at page 3, lines 4 to 5.

in order for it to be supported, or justified."[195] In *CSR Building Products Limited v United States Gypsum Company*, the delegate took the following approach to determine whether the claimed matter is supported by the matter disclosed in the specification:

(a) Construe the claims to determine the scope of the invention claimed.

(b) Construe the description and the technical contribution to the art, that is how far the concept has carried forward the state of the art.

(c) Decide whether the claims are supported by the technical contribution to the art. [196]

252. The Federal Court has approved of this approach.[197]

253. The gist of the opponent's primary submission is that the specification does not disclose an invention at all and, furthermore, that Mr Eaton did not cogently explain how the opposed applications deliver any *"benefit, advantage or non-obvious useful alternative"*. Therefore, to the extent that the embodiments given in the specification constitute some technical contribution, then the claims are much broader than those embodiments and so are not supported.[198] They also submitted that the specification consistently emphasises the role and importance of the "locating protrusions" or "nasal locators". There is no embodiment described that omits nasal locators, or what equivalent modifications could be made.[199] The opponent considered this to be a departure from what was described and shown in the figures.

254. The applicant criticised the opponent's approach, noting that there is no requirement that the specification identify the technical contribution, nor that the applicant's expert identify such when the opponent's expert did not mount such an attack. The onus of establishing the ground of opposition lies with the opponent. The also noted that the opponent's submissions do not grapple with the actual test of whether the claims claim results that are not enabled by the specification.[200] In this regard they noted that the opponent had not pressed the ground of sufficiency, and therefore may be taken to accept that the claims are enabled across their full breadth.[201]

255. I do not share the concerns of the applicant on the latter point. Sufficiency and support (inasmuch as it equates to "Biogen insufficiency") are "two sides of the same coin".[202] It is therefore reasonable that a party may choose to argue one ground in preference to another depending on the facts of the case. However, I agree with the applicant that the opponent's submissions do not engage with the key considerations under support. This is perhaps a consequence of the apparent difficulties Mr Palkon had with the terminology used in the specifications. Admittedly that may have been the result of an over-meticulous or over-technical approach to construction,[203] but, ultimately, if Mr Palkon is unable to determine what the invention actually is, then he will hardly be in a position to provide a definitive opinion on where the technical contribution lies.

---

[195] *EXXON/Fuel Oils* (T409/91) [1994] OJ EPO 653.
[196] [2015] APO 72 at [115].
[197] See for example, *Cytec Industries Inc v Nalco Company* (2021) 162 IPR 202.
[198] OS at [234] to [235].
[199] OS at [236].
[200] AS at [262].
[201] AS at [260].
[202] *Merck Sharp & Dohme Corporation v Wyeth LLC (No 3)* [2020] FCA 1477 at [543].
[203] AS at [58].

256. The applicant's submissions on support at the hearing did not explicitly identify the technical contribution to the art. Nevertheless, at the hearing, the applicant submitted that the crux of the invention lies in the stability provided by the seal formed around the sides and base of the nose by inflation of the mask. They referenced the discussion in the specification of a specific embodiment at page 18,[204] but my understanding is that they did not consider the stability was dependent on all of the additional features present in that embodiment (including the nasal locators and perimeter portions).

257. Similarly, the applicant submitted, albeit in relation to the ground of clarity (and the definition of the stiffer exterior side) rather than support:

> "So the person skilled in the relevant art, reading the claim and the body of the specification would readily appreciate that, ***in order for the inflatable nasal seal to work, it has (by comparison to the exterior surface) a supple face-contacting side that can conform to the surfaces of the nose of the wearer.*** By comparison, the exterior side does not have to do that, but *will* have to provide some structural support so as to allow movement of air gases into the nose without blocking the nostrils (ie, keep the exterior side sufficiently away from the interior side and nose to allow for gasses to flow properly) ***and to provide sufficient structure for the supple interior side to be held in position across the bottom of the nose and across the sides of the nose as claim 1 requires***" [emphasis added].[205]

258. Given the applicant's submissions, it seemed to me that the technical contribution to the art may lie in the arrangement of the central and side portions, and the use of a supple material, which, on inflation of the mask by internal gases, wraps around and seals to the user's nose, including the surfaces of the sides of the nose. This provides for greater stabilisation of the mask during use. That being the case, the claims of the present applications, *with the exception of '841*, would be consistent with that technical contribution.

259. In the case of '841, the claims do not include the feature of the face contacting side of the seal being supple to conform under internal pressure to the surfaces of the nose of the wearer, including at the side portions of the seal, to outside surfaces of the sides of the nose. This feature constitutes part of the technical contribution to the art that I identified above.

260. The opponent did not specifically identify this as an issue in their grounds of opposition to '841, but it is open to the Commissioner under section 60(3) to take into regard any ground on which the grant of a patent may be opposed, whether relied on by the opponent or not. As the parties had not had the opportunity to address this specific issue, I sought written submissions on whether the claims of '841 are supported.

261. In response, the applicant conceded the support issue and indicated that they would make amendments to '841 once a determination of the substantive opposition is made. However, the opponent went broader than the specific concern I raised and questioned the suggested technical contribution. They considered that the submissions made by the applicant, and the reliance on the discussion at page 18 resulted in the claims of all the applications lacking support. The gist of their submissions is that:

---

[204] Specification at page 18, lines 21 to 31.
[205] AS at [254].

- There is nothing in any of the specifications that suggests that the passage at page 18, lines 21 to 31 was important, or sought to identify any relevant advance over the prior art;

- The applicant did not identify anything described in the page 18 paragraph as being a relevant technical contribution or advance over the prior art in its written outline;

- The applicant did not reference any expert evidence setting out a view that what was described in the page 18 paragraph represented an advance in the state of the art; and,

- The assertion that the page 18 paragraph represented the crux of the invention was not taken forward or developed when the applicant sought to deal with the support ground or with inventive step.

262. They went on to state that even if it could be assumed that the page 18 paragraph identifies a relevant technical contribution to the art, then it can be seen to include features additional to those I suggested to constitute the technical contribution:

- There must be "nasal locators" whose position can be decoupled from the position of the mask body;

- There must be a seal that forms between the specified supple interior walls (above, below and to each side of the nasal locators), and the outside surfaces of the nose of the wearer, the lower face of the nose, and the upper lip;

- There must be a supple perimeter that is of a shape and design capable of achieving the decoupling without breaking the seal.

263. The opponent submitted that none of the applications included claim integers directed to any of these features or include relevant functional language directed to decoupling. They went on to suggest that such language would also likely raise separate clarity issues because the degree of decoupling is not defined.

264. Perhaps consistent with their primary arguments that the applications do deliver any *"benefit, advantage or non-obvious useful alternative"*, the opponent then went on to submit that:

> "Moreover to the extent that only some decoupling effect is being (indirectly) referenced, that is, decoupling to any degree, then that is inherently present in any inflatable mask as the inflatable part of the seal is necessarily flexible and so must allow at least some degree of relative movement of the seal relative to the mask body (see also Palkon 1 para 389, not responded to or disputed by Mr Eaton). There is no advance in the art at all.
>
> That position is even clearer if the 'technical contribution' is asserted to be the mere sealing around the user's nose with no decoupling effect (noting that your page two paragraph does not reference any decoupling effect) – that is how every inflatable nasal mask works (see for example Palkon 1 paragraphs 183-4)."

265. Finally, the opponent also noted that the page 18 passage required that the seal also conform to the upper lip of the wearer immediately below the nose. They noted that the applicant's written and verbal submissions asserted that the claims were not limited to such the arrangement described in this embodiment.

266. On balance I do not find the opponent's submissions on this point to be persuasive.

267. A significant point of difference lies in the weight that is given to the "consistory clauses" in the Summary of the Invention. Nasal locators are not mentioned in the broadest aspects of the invention,[206] and appear only in further aspects later in the summary.[207] The opponent's submissions drew on embodiments described in the Detailed Description of the invention and the illustrative figures. They gave the consistory clauses little weight, arguing that the applicant's arguments that nasal locators were optional was a matter of form rather than substance.

268. I agree that consistory clauses do not necessarily provide a definitive statement of what the invention. However, as noted by the applicant, there is no requirement that the specification explicitly state what the technical contribution is or where the inventive step lies. Nor is the applicant limited only to their specific examples. The key consideration lies in whether the specification claims extend to subject matter which after reading the specification (as a whole), would still not be at the disposal of the person skilled in the art. That is, the patent must enable the invention to be performed by such a person.[208] One way for a claim to exceed the technical contribution to the art is for the claim to cover ways of achieving the desired result which owe nothing to the patent or any principle that it discloses.[209] However, applicants can also rely upon a principle of general application if it would appear reasonably likely to enable the whole range of products within the scope of the claim to be made.[210]

269. The detailed description is clearly drafted to illustrate the invention by way of various preferred embodiments and specific examples. The discussion at page 18 relates to preferred embodiments which include a supple perimeter portion. The properties of the seal, including the manner in which the decoupling of the exterior face from the interior face, are specific to embodiments comprising that feature, though, as suggested by the opponent, decoupling in such a manner might be an inherent property of masks having a supple interior side.

270. On the other hand, the side portions of the mask are said to engage with the patient's nose, to form an additional seal and support the location of the mask. The properties imparted by this configuration are not specific to the particular embodiment – all of the seals described in the specifications include such side portions and therefore would possess the same properties. In my opinion this feature, and the improved stability of the mask seal that it provides, is the principle of general application underpinning the present invention.

271. To the extent that the mask must incorporate nasal locators, it is undisputed that, as a nasal mask, the device must provide a means of delivering air to the nares of the user. No evidence was provided specific to the meaning of "nasal locator" and whether it is a term in the art. But besides their eponymous function, the specification states that the nasal locators are designed to *extend into or sit about* the user's nostrils, and act as ports for the supply of air to the nares.[211] It would seem to me that this particular definition would mean that any air ports designed to lie adjacent the nose would also act as nasal locators.

---

[206] For example, at page 1, lines 23 to 30.
[207] Page 4, lines 20 to 22.
[208] *TCT Group Pty Ltd v Polaris IP Pty Ltd* [2022] FCA 1493 at [243]-[244].
[209] *Ibid* at [245], citing *Jusand Nominees Pty Ltd v Rattlejack Innovations Pty Ltd* [2022] FCA 540; 167 IPR 1 at [483].
[210] Regeneron Pharmaceuticals Inc v Kymab Ltd [2020] UKSC 27; RPC 22 at
[211] Specification at page 22, lines 32 to 34.

272. Moreover, Mr Eaton stated that the skilled person would understand that the mask could be designed with or without nasal locators, and the configuration of key features of the seal contacting the user's face would be the same with or without nasal locators.[212] Neither Mr Palkon (in the first instance) nor Mr Eaton considered that the nasal locators perform a sealing function, with Mr Palkon further stating that they are simply required to locate the mask.[213] The specific configuration of the air supplying ports therefore would not appear relevant to achieving the seal around the user's nose, and in that way does not constitute *"a variable which significantly affects the value or utility of product in achieving the purpose for which it is to be made"*.[214]

273. For completeness, I note that Mr Palkon went on to state in his EIR that the skilled person would not design a mask of the present type without nasal locators because they are required to keep the seal in place and avoid unwanted deformation. To that end he noted that the discussion at page 18 states that *"the supple perimeter de-couples the position of the nostril locators from the position of the mask body, allowing the mask body to displace both laterally and vertically (relative to axes of the patient's face)"*. Mr Palkon considered that this requires a relationship between the locators and the suppleness of the seal that would not be present if the nasal locators were not present.[215] I do not agree with Mr Palkon's conclusion here. As submitted by the applicant at hearing, this passage merely explains how the nasal locators stay in position because of the suppleness of the seal in the particular embodiment comprising a supple periphery. I therefore do not consider that this evidence is relevant in the determination.

274. On the issue of the seal conforming to the upper lip immediately below the base of the nose, I do not find the opponent's submissions persuasive. Admittedly, it is difficult to envisage a seal having the features of the present claims that would not contact at least some portion of the upper lip area immediately below the nose. In this regard the feature in question could well be considered an implicit feature of the invention (or indeed of any below-the-nose mask), and neither expert appears to have had any concerns in relation to this feature (or its absence). But in any case, as I have determined above, the principle of general application relates to the arrangement of the central and side portions, and in particular the incorporation of the side portions and the additional stability these provide to the seal. This stability is independent of any contact between the seal and the upper lip of the user. I do not consider that the claims exceed this technical contribution.

275. In short, I am satisfied that the technical contribution lies in a nasal seal, the seal including a face contacting side, the seal being formed of a soft flexible material, and including a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each side portion extending across a side of the nose, the face contacting side of the seal being supple to conform under internal pressure to the surfaces of the nose of a wearer, including, at the side portions of the seal, to outside surfaces of the sides of the nose.

276. The claims of '841 do not include all these features, and therefore exceed the technical contribution. However, I consider the claims of '628, '838, '840, '842 and '843 are supported.

Succinctness

---

[212] Eaton 1 at [148].
[213] Palkon 1 at [167], Eaton 1 at [148].
[214] *Regeneron Pharmaceuticals Inc v Kymab Ltd* [2020] UKSC 27; RPC 22 at [56], cited with approval by the Full Court in *Jusand Nominees Pty Ltd v Rattlejack Innovations Pty Ltd* [2023] FCAFC 178.
[215] Palkon 2 at 93.

277. In addition to clarity and support, Section 40(3) requires that the claims be succinct.

278. The opponent referred to the decision of the Deputy Commissioner in *Sabre Inc. v Amadeus Global Travel Distribution SA*,[216] wherein the Deputy Commissioner said that it had been long accepted that if the repetitious nature of the claims is such that the difference in scope between different claims is not readily apparent, then the claims as a whole may be found to lack succinctness. The opponent submitted that there is a strong public interest in the public having the ability to readily determine what the asserted scope of monopoly is without having to work through a complicated, overlapping thicket of patent claims. They argued that the "extraordinary" number of claims, and their overlapping nature, in the growing family of patents and applications means that this is an unusual case in which there is a strong basis for rejecting the applications for failing to comply with the succinctness requirement of section 40(3).[217]

279. I do not find these submissions persuasive. As noted by the Deputy Commissioner in *Sabre v Amadeus* at [17]:

> "While the number of claims, and particularly the number of independent claims, in this case would readily suggest undue prolixity given the nature of the invention said to be described, one ought to be cautious in applying arbitrary limits to the applicant's legitimate freedom to draft claims that meet the requirements of the Act. As Hely J stated in *Doric Products Pty Ltd v Lockwood Security Products Pty Ltd* [2001] FCA 1877:
>
> > 'I accept that it takes patience, time and effort to unravel all of the claims of the Patent. Subject to the expenditure of that time and effort, there is no alleged ambiguity in the claims. The problem is not with prolixity, but with attempted compression, and the multitude of claims. That, however, falls short of establishing that the claim or claims are not clear and succinct'
>
> In that case only 33 claims were present but the principle that clarity and succinctness are not generally a factor of the effort that may be involve in construing an extensive set of claims seems to be generally applicable. However, it has long been accepted that claims will not be clear and succinct if their repetitious nature is such the difference in scope between two or more claims is not readily apparent, (see *Bancroft's Application*, (1906) 23 RPC 89). This situation rarely arises in practice but I think the present application is one such case because of the large number of different combinations of features claimed and the wide variety and ambiguity of the different terminology in the claims that is said to define the same key features."

280. Notably, Sabre's application comprised 101 claims, including 16 independent claims and dependent claim groups, and 9 omnibus claims. None of the present applications individually presents such complexity. Each application consists of only a single independent claim, and there is no real suggestion that the individual claim sets are unduly prolix. As noted by the applicant,[218] the opponent's arguments proceed on the premise that when considering whether the claims are succinct, regard may be had to other patent applications in the patent family. I

---

[216] [2004] APO 21.
[217] OS at [238] to [240].
[218] AS at [271].

see no basis in section 40(3) for such an approach. The assessment is made on the specification in isolation of other related family members. The opposition is unsuccessful on this ground.

Utility

281. Section 18(1)(c) of the Act requires that the claimed invention be useful. A summary of relevant principles was provided by the Full Court of the Federal Court in *Artcraft Urban Group v Streetworx*:

> "It is 'no objection' to the validity of an innovation patent granted under the Act that it is 'commercially impracticable'. The utility of the patent depends upon whether, by following the teaching of the specification, the result claimed is produced.
>
> The 'basic principle' of inutility is that if an invention 'does what it is intended by the patentee to do, and the end attained is itself useful, the invention is a useful invention' … What the invention is intended to do is a matter to be gathered from the 'title and the whole of the specification.
>
> Put another way, the two questions are: first, what is the promise of the invention derived from the whole of the specification?; second, by following the teaching of the specification, does the invention, as claimed in the patent, attain the result promised for it by the patentee? … Further, 'everything' that is within the scope of a claim must be useful, that is, attain the result promised for the invention by the patentee."[219] [citations omitted]

282. Section 7A also requires that an invention is taken to not be useful unless a specific, substantial and credible use for the invention (so far as claimed) is disclosed in the complete specification. The Explanatory Memorandum to the *Raising the Bar* Act explained that:

- "specific" means a use specific to the subject matter claimed so as to "provide a well-defined and particular benefit to the public";
- "substantial" means the claimed invention does not require further research to identify or reasonably confirm a "real world use"; "an application must show that an invention is useful to the public as disclosed in its current form, not that it prove useful at some future date after further research";
- an asserted use will be "credible" unless there is evidence that the invention is inoperative (i.e., does not operate to produce the results claimed by the patent application) or there is reason to doubt the objective truth of the statements in the specification.[220]

283. The gist of the opponent's submissions under the ground of utility were much the same as those made under the ground of clarity in relation to the definition of regions that are much stiffer than the supple exterior side, and that those regions extend into the side portions of the seal. They submitted that there is a complete lack of detail about those regions,[221] and what logically follows is that even if the claims include subject matter that is relevantly useful, the claims must also include matter that is not useful.

---

[219] *Artcraft Urban Group Pty Ltd v Streetworx Pty Ltd* [2016] FCAFC 29 at [118]-[121].
[220] Explanatory Memorandum, Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 (Cth), pages 44-45.
[221] OS at [243].

284. The applicant submitted that, according to the applications, an object of the invention is to provide a patient interface (or aspects thereof) which will at least provide the public with a useful choice.[222] No further promise is made in the specification.[223] The applications meet that promise by providing an alternative CPAP interface design including an inflatable nasal seal design.

285. I agree with the applicant that the specification does not make any promise beyond the provision of a useful alternative, and to that extent the requirements of section 18(1)(c) have been met. Furthermore, the opponent's submissions in relation to the lack of detail in the definition of the regions appear to go to the issue of clarity. I have determined that the claims do not lack clarity as a result of the same terms, and I do not consider that a different outcome is achieved under the ground of utility. But, in any case, the opponent's submissions based on the assertion that the side portions comprising stiffer regions appears based on Mr Palkon's evidence that he could distinguish the present features from those of prior art seals, rather than whether they were useful or not.

286. In summary, the opponent has not made out this ground of opposition.

Manner of manufacture

287. Section 18(1)(a) of the Act requires that the invention, so far as claimed in any claim, must be a manner of manufacture within the meaning of section 6 of the Statute of Monopolies. My understanding is that the opponent's submissions on this ground relate to the definition of the "stiffer regions" of the mask. The gist of their arguments is that the present invention is a mere collocation of integers[224] and the required interaction between the components to achieve an overall useful result[225] is not specified in the claims.

288. The applicant noted that the opponent's submissions on this point were not supported by any explanation or reference to Mr Palkon's evidence. They argued that there is no requirement that the claims disclose or specify the interaction between the various features. That aside, the authorities cited by the opponent and the examples of cases referred to in the Patent Manual of Practice and Procedure are clearly distinguishable from the present case as they related to inventions that were completely separate processes or substances.[226] In this regard, the applicant referred to Mr Eaton's statements that there is significant ingenuity involved in nasal seal design precisely because there is an interrelationship between the features of the mask, and variations can have significant effects.[227] Similarly Mr Palkon stated in relation to his design experience, that modifications to thicknesses of silicone seal layers had certain flow-on effects on deformation and supporting the remaining silicone layers, as well as the interrelationship between the seal and the headgear.[228]

---

[222] Specification, page 1, lines 21 to 22.
[223] AS at [224].
[224] Patent Examiner's Manual of Practice and Procedure at 2.9.2.16.1.
[225] *Smith & Nephew Pty Ltd v Wake Forest University Health Sciences* (2009) 82 IPR 467 at [21] to [23], citing with approval previous authorities *Re Klaber's Patent* (1906) 23 RPC 461, *Palmer v Dunlop Perdriau Rubber Co Ltd* (1937) 59 CLR 30 at 73, and *British Celanese Ltd v Courtaulds Ltd* (1935) 52 RPC 171.
[226] AS at [215] to [216].
[227] Eaton 1 at [59] and [87].
[228] Palkon 1 at [33] to [39].

289. On balance I find the applicant's submissions persuasive. The different features of the masks clearly have a working interrelationship and are not a mere collocation of parts. The claims are therefore for a manner of manufacture.

Conclusion

290. The opposition is unsuccessful on the grounds pressed by the opponent at the hearing.

291. However, I have found that the claims of '841 are not supported as the claims of '841 do not include the feature of the face-contacting side of the seal being supple to conform under internal pressure to the surfaces of the nose of the wearer, including, at the side portions of the seal, to outside surfaces of the sides of the nose.

292. I consider that this issue may be overcome by amendment. I therefore give the applicant two (2) months from the date of this decision to propose amendments to overcome the issue.

293. Subject to appeal, I direct that '628, '838, '840, '842 and '843 proceed to grant.

Costs

294. Costs generally follow the event. However, while the opposition has not been successful on the grounds raised by the opponent at the hearing, I have found that the claims of '841 are not supported.

295. Under the circumstances I consider it appropriate to allow the parties the opportunity to make written submissions on the award of costs. I give the parties two (2) weeks to provide such submissions.

L.F. McCaffery
Delegate of the Commissioner of Patents

Application 2020223628 Claims

1. An inflatable nasal seal for a patient interface:

the seal including a face contacting side, the seal being formed of a soft flexible material, and including a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each side portion extending across a side of the nose,

the face contacting side of the seal being supple to conform under internal pressure to the surfaces of the nose of a wearer, including, at the side portions of the seal, to outside surfaces of the sides of the nose,

an exterior side of the seal including regions much stiffer than the supple interior side, the regions extending into the side portions of the seal.

2. The inflatable nasal seal according to claim 1, wherein the regions much stiffer than the supple interior side are formed of thicker material than the face contacting side.

3. The inflatable nasal seal according to claim 1 or 2, wherein the supple portions of the seal comprise a silicone material with a thickness between 0.05mm and 0.5mm.

4. The inflatable nasal seal according to claim 1 or 2, wherein the supple portions of the seal comprise an elastomer with a thickness between 0.1mm and 0.2mm.

5. The inflatable nasal seal according to any one of claims 1 to 4, wherein the regions much stiffer than the supple interior side of the seal comprise a silicone material with a thickness between 2mm and 5mm.

6. The inflatable nasal seal according to any one of claims 1 to 4, wherein the regions much stiffer than the supple interior side of the seal comprise an elastomer with a thickness between 2mm and 3mm.

7. The inflatable nasal seal according to any one of claims 1 to 6, wherein the regions much stiffer than the supple interior side include a composite material or combination of parts.

8. The inflatable nasal seal according to any one of claims 1 to 7, wherein the regions much stiffer than the supple interior side include a reinforcement or a flexible insert of stiff material.

9. The inflatable nasal seal according to claim 8, wherein the insert of stiff material is integrated to a mask body.

10. The inflatable nasal seal according to any one of claims 1 to 9, wherein the exterior side of the central portion of the seal includes an opening for passing gases to and from the interior of the seal.

11. The inflatable nasal seal according to claim 10, wherein the opening is configured to be fitted to a mask body, or directly to a conduit extending through a mask body.

12. The inflatable nasal seal according to claim 10 or 11, wherein the opening includes lips and/or channels to engage with channels and/or lips on the mask body.

13. The inflatable nasal seal (301) according to claim 10 or 11, wherein the opening is formed with clip portions, or clip portions are attached to or over-moulded to a perimeter of the opening to facilitate engagement with the mask body.

14. The inflatable nasal seal according to any one of claims 10 to 13, wherein the central portion extends above and below the opening, the central portion including regions above and below the opening that are thin and supple.

15. The inflatable nasal seal according to any one of claims 10 to 14, wherein above the opening, the central portion includes an outer-facing wall, an inward-facing wall and a perimeter portion, wherein at least the inward-facing wall and the perimeter portion are thin and supple.

16. The inflatable nasal seal according to any one of claims 10 to 15, wherein below the opening, the central portion includes an outer wall portion, an inner wall portion and a peripheral portion, wherein at least the inner wall portion and the peripheral portion are thin and supple.

17. The inflatable nasal seal according to claim 1 or 2, wherein the supple portions of the seal comprise a silicone material with a thickness between 0.05mm and 0.5mm, and wherein the exterior side of the central portion of the seal includes an opening for passing gases to and from the interior of the seal, and below the opening, the central portion includes an outer wall portion, an inner wall portion and a peripheral portion, wherein at least the inner wall portion and the peripheral portion are thin and supple.

18. The inflatable nasal seal according to any one of claims 1 to 17, wherein the regions much stiffer than the supple interior side resist outward flexing of the side portions of the seal when the seal is inflated under pressure.

19. The inflatable nasal seal according to any one of claims 1 to 18, wherein the side portions provide resistance to flexing with an effective stiffness of at least 1N force at the end of the regions much stiffer than the supple interior side to flex the side portion through an angle of about 60°.

20. The inflatable nasal seal according to any one of claims 1 to 19, wherein the side portions of the seal are substantially parallel to each other and substantially normal to the central portion of the seal.

21. The inflatable nasal seal according to any of claims 1 to 20, wherein an overall plan form of the seal is parabolic, half elliptical, half oval or U-shaped.

22. The inflatable nasal seal according to any of claims 1 to 21, wherein the seal curves about and does not extend over the region of the user's nasal bridge.

23. The inflatable nasal seal according to claim 1 or 2, wherein the exterior side of the central portion of the seal includes an opening for passing gases to and from the interior of the seal, and below the opening, the central portion includes an outer wall portion, an inner wall portion and a peripheral portion, wherein at least the inner wall portion and the peripheral portion are thin and supple, and wherein the seal curves about and does not extend over the region of the user's nasal bridge.

24. The inflatable nasal seal according to claim 1 or 2, wherein the supple portions of the seal comprise a silicone material with a thickness between 0.05mm and 0.5mm, wherein the exterior side of the central portion of the seal includes an opening for passing gases to and from the interior of the seal, and below the opening, the central portion includes an outer wall portion, an inner wall portion and a peripheral portion, wherein at least the inner wall portion and the peripheral portion are thin and supple, and wherein the seal curves about and does not extend over the region of the user's nasal bridge.

25. The inflatable nasal seal according to any one of claims 1 to 24, wherein the seal has an overall width from outside surface of one side portion to outside surface of the other side portion of between 30mm and 60mm.

26. The inflatable nasal seal according to any one of claims 1 to 25, wherein the seal has an overall depth, from the outer surface of the central portion to a line joining the extreme ends of

each side portion, between 40mm and 65mm.

27. The inflatable nasal seal according to any one of claims 1 to 26 including an extension to go over the user's mouth.

28. The inflatable nasal seal according to claim 27, wherein the extension includes an outlet directed to the user's mouth.

29. A patient interface comprising the inflatable nasal seal according to any one of claims 1 to 28.

30. An assembly comprising the inflatable nasal seal according to any one of claims 1 to 28 supported by a mask body, the mask body being formed of a material more rigid than the nasal seal.

31. The assembly according to claim 30, wherein the mask body together with the seal forms an enclosure having an inlet opening and a patient outlet opening.

32. The assembly according to claim 30, wherein the seal is permanently attached to the mask body.

33. The assembly according to claim 32, wherein the seal is attached by overmoulding or bonding.

Application 2021201838 Claims

1. A nasal seal for a patient interface:

the seal including a face contacting side and an exterior side, the seal being formed of a soft flexible material, and including a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, the side portions extending across a side of the nose,

the face contacting side of the seal being supple to conform under internal pressure to the surfaces of the nose of a wearer, including at the side portions of the seal, to outside surfaces of the sides of the nose,

wherein the side portions each include an outward face portion and an inward face portion and a peripheral edge portion that joins the inward face portion and the outward face portion.

2. The nasal seal according to claim 1, wherein the seal is inflatable.

3. The nasal seal according to claim 1 or 2, wherein the exterior side of the seal includes regions much stiffer than the supple interior side, the regions extending into the side portions of the seal.

4. The nasal seal according to claim 3, wherein the outward face portions include the regions much stiffer than the supple interior side.

5. The nasal seal according to claim 3 or 4, wherein the regions much stiffer than the supple interior side are formed of thicker material than the face contacting side.

6. The nasal seal according to any one of claims 3 to 5, wherein the regions much stiffer than the supple interior side have a stiffness corresponding to a silicone material with a thickness between 2mm and 5mm and a Shore A hardness of 40.

7. The nasal seal according to any one of claims 3 to 6, wherein the regions much stiffer than the supple interior side include a composite material or combination of parts.

8. The nasal seal according to any one of claims 3 to 7, wherein the regions much stiffer than the supple interior side include a reinforcement or a flexible insert of stiff material.

9. The nasal seal according to claim 8, wherein the insert of stiff material is integrated to a mask body.

10. The nasal seal according to any one of claims 1 to 9, wherein the supple portions of the seal comprise a silicone material with a thickness between 0.05mm and 0.5mm.

11. The nasal seal according to any one of claims 1 to 9, wherein the supple portions of the seal comprise an elastomer with a thickness between 0.1mm and 0.2mm.

12. The nasal seal according to any one of claims 1 to 11, wherein the regions much stiffer than the supple interior side of the seal comprise a silicone material with a thickness between 2mm and 5mm.

13. The nasal seal according to any one of claims 1 to 11, wherein the regions much stiffer than the supple interior side of the seal comprise an elastomer with a thickness between 2mm and 3mm.

14. The nasal seal according to any one of claims 1 to 13, wherein the outward face portions have a thickness between 2mm and 5mm.

15. The nasal seal according to claim 14, wherein the outward face portions have a thickness between 3mm and 5mm.

16. The nasal seal according to any one of claims 1 to 15, wherein the peripheral edge portions extend around a top edge, an end edge and a lower edge.

17. The nasal seal according to any one of claims 1 to 16, wherein the side portions resemble a pocket when considered from inside the seal.

18. The nasal seal according to any one of claims 1 to 17, wherein the exterior side of the central portion of the seal includes an opening for passing gases to and from the interior of the seal.

19. The nasal seal according to claim 18, wherein the opening is configured to be fitted to a mask body, or directly to a conduit extending through a mask body.

20. The nasal seal according to claim 18 or 19, wherein the opening includes lips and/or channels to engage with channels and/or lips on the mask body.

21. The nasal seal according to claim 18 or 19, wherein the opening is formed with clip portions, or clip portions are attached to or over-moulded to a perimeter of the opening to facilitate engagement with the mask body.

22. The nasal seal according to any one of claims 18 to 21, wherein the central portion extends above and below the opening, the central portion including regions above and below the opening that are thin and supple.

23. The nasal seal according to any one of claims 18 to 22, wherein above the opening, the central portion includes an outer-facing wall, an inward-facing wall and a perimeter portion, wherein at least the inward-facing wall and the perimeter portion are thin and supple.

24. The nasal seal according to any one of claims 18 to 23, wherein below the opening, the central portion includes an outer wall portion, an inner wall portion and a peripheral portion, wherein at least the inner wall portion and the peripheral portion are thin and supple.

25. The nasal seal according to any one of claims 1 to 24, wherein the outward face portions resist outward flexing of the side portions of the seal when the seal is inflated under pressure.

26. The nasal seal according to any one of claims 1 to 25, wherein the side portions of the seal are substantially parallel to each other and substantially normal to the central portion of the seal.

27. The nasal seal according to any one of claims 1 to 26, wherein an overall plan form of the seal is parabolic, half elliptical, half oval or U-shaped.

28. The nasal seal according to any one of claims 1 to 27, wherein the seal curves about and does not extend over the region of the user's nasal bridge.

29. The nasal seal according to any one of claims 1 to 28, wherein the seal has an overall width from outside surface of one side portion to outside surface of the other side portion of between 30mm and 60mm.

30. The nasal seal according to any one of claims 1 to 29, wherein the seal has an overall depth, from the outer surface of the central portion to a line joining the extreme ends of each side portion, between 40mm and 65mm.

31. The nasal seal according to any one of claims 1 to 30 including an extension to go over the user's mouth.

32. The nasal seal according to claim 31, wherein the extension includes an outlet directed to the user's mouth.

33. A patient interface comprising the nasal seal according to any one of claims 1 to 32.

34. The patient interface according to claim 33 including a mask body assembled to the seal, the body being formed of a material more rigid than the seal, and together with the seal forming an enclosure having an inlet opening and a patient outlet opening.

35. The patient interface according to claim 34 further including a swivelling elbow connected to the inlet opening.

36. An assembly comprising the nasal seal according to any one of claims 1 to 32 supported by a mask body, the mask body being formed of a material more rigid than the nasal seal.

37. The assembly according to claim 36, wherein the mask body together with the seal forms an enclosure having an inlet opening and a patient outlet opening.

38. The assembly according to claim 36 or 37, wherein the seal is permanently attached to the mask body.

39. The assembly according to claim 38, wherein the seal is attached by overmoulding or bonding.

Application 2021201840 Claims

1. A patient interface comprising:

a nasal seal including a face contacting side, the seal being formed of a soft flexible material, and including a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each side portion extending across a side of the nose,

the face contacting side of the seal being supple to conform under internal pressure to the surfaces of the nose of a wearer, including, at the side portions of the seal, to outside surfaces of the sides of the nose,

an exterior side of the seal including regions much stiffer than the supple interior side, the regions extending into the side portions of the seal,

a mask body assembled to the seal, the mask body formed of a material more rigid than the seal, and together with the seal forming an enclosure having an inlet opening and a patient outlet opening.

2. The patient interface according to claim 1, wherein the seal is inflatable.

3. The patient interface according to claim 1 or 2, wherein the seal is permanently attached to the mask body.

4. The patient interface according to claim 3, wherein the seal is attached by overmoulding or bonding.

5. The patient interface according to any one of claims 1 to 4, wherein the seal includes overmoulded or bonded rigid plastic barbs configured to clip into correspondingly shaped recesses formed in the mask body and hold the nasal seal in sealing engagement with the mask body.

6. The patient interface according to any one of claims 1 to 4, wherein the seal has a periphery that is formed with an overmoulded or bonded rigid plastic looped clip configured to clip to the mask body.

7. The patient interface according to any one of claims 1 to 4, wherein the mask body includes a nasal seal engaging portion that engages the exterior side of the seal.

8. The patient interface according to any one of claims 1 to 4, wherein the seal comprises an

opening and the mask body comprises a seal opening for engaging with the opening of the seal.

9. The patient interface according to claim 8, wherein the opening of the seal is in an outwardly facing wall of the central portion of the seal.

10. The patient interface according to claim 9, wherein the opening of the seal includes features to engage with complementary features on the mask body.

11. The patient interface according to claim 10, wherein the feature on the opening of the seal are lips and/or channels and the complementary features on the mask body are channels and/or lips.

12. The patient interface according to any one of claims 1 to 11, wherein the opening of the seal is commensurate with the extent of the mask body, this extent being commensurate with the general width of the patient interface and approximately with the width of the nose of the intended wearer.

13. The patient interface according to any one of claims 1 to 12, wherein a region adjacent and including an opening of the seal is much stiffer than the rest of the seal.

14. The patient interface according to any one of claims 1 to 13, wherein a region adjacent and including an opening of the seal is formed thicker in the same material than the rest of the seal.

15. The patient interface according to any one of claims 1 to 14, wherein a region adjacent and including an opening of the seal is formed of a stiffer material than the rest of the seal.

16. The patient interface according to any one of claims 1 to 15, wherein the central portion extends above and below an opening, the central portion including regions above and below the opening that are thin and supple.

17. The patient interface according to any one of claims 1 to 16, wherein above an opening, the central portion includes an outer-facing wall, an inward-facing wall and a perimeter portion, wherein at least the inward-facing wall and the perimeter portion are thin and supple.

18. The patient interface according to any one of claims 1 to 17, wherein below an opening, the central portion includes an outer wall portion, an inner wall portion and a peripheral portion, wherein at least the inner wall portion and the peripheral portion are thin and supple.

19. The patient interface according to any one of claims 1 to 18, wherein the side portions each include an outward face portion and an inward face portion and a peripheral edge portion that joins the inward face portion and the outward face portion.

20. The patient interface according to claim 19, wherein the peripheral edge portions of the seal allow the mask body to displace both laterally and vertically relative to axes of the patient's face.

21. The patient interface according to any one of claims 1 to 20, wherein the seal includes an extension to go over the user's mouth.

22. The patient interface according to claim 21, wherein the extension includes an outlet directed to the user's mouth.

23. The patient interface according to any one of claims 1 to 22, wherein the mask body includes at least one strap engaging portion from which extends a loop strap to secure the interface to the patient.

24. The patient interface according to claim 23, wherein a central portion of the mask body defines a convex shape generally matching a convex shape of an outwardly facing wall of the seal, with the strap engaging portion extending from a lateral extreme of the central portion, the strap engaging portion extending away from the central portion at an angle outwardly aligned relative to the general convex shape.

25. The patient interface according to any one of claims 1 to 22, wherein the mask body includes connector portions for engagement with connector portions of a head strap.

26. The patient interface according to claim 23 or 24, including at least two strap engaging portions, wherein each strap engaging portion extends laterally away from the inlet opening, from opposite sides of the inlet opening.

27. The patient interface according to any one of claims 1 to 26, wherein the mask body includes a socket for connecting with a supply conduit.

28. The patient interface according to any one of claims 1 to 27, wherein the mask body is made from a plastics material.

29. The patient interface according to claim 28, wherein the mask body is made from polycarbonate or silicone

30. The patient interface according to any one of claims 1 to 29, wherein the mask body includes small apertures as part of a gas washout vent.

31. The patient interface according to any one of claims 1 to 30, wherein the regions much stiffer than the supple interior side as well as the supple interior side comprise a silicone material, and/or comprise a neoprene material.

32. The patient interface according to any one of claims 1 to 31, wherein the regions much stiffer than the supple interior side and the supple interior side are formed in the same material.

33. The patient interface according to any one of claims 1 to 32, wherein the regions much stiffer than the supple interior side are formed thicker in the same material as the rest of the seal.

34. The patient interface according to claim 33, wherein the regions much stiffer than the supple interior side taper in thickness to reach the thickness of the interior side.

Application 2021201841 Claims

1. A patient interface comprising:

an inflatable nasal seal including a face contacting side, the seal being formed of a soft flexible material, and including a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each side portion extending across a side of the nose,

a mask body connected to the seal, including a seal engaging portion that engages an exterior side of the seal, a mask body inlet opening and at least two strap engaging portions, each strap engaging portion extending laterally away from the mask body inlet opening, from opposite sides of the mask body inlet opening.

2. The patient interface according to claim 1, wherein the central portion of the mask body defines a convex shape generally matching a convex shape of an outwardly facing wall of the seal.

3. The patient interface according to claim 2, wherein the strap engaging portions extend away from the central portion at an angle outwardly aligned relative to the general convex shape.

4. The patient interface according to any one of claims 1 to 3, wherein the strap engaging portions diverge from an outwardly facing wall of the seal.

5. The patient interface according to claim 4, wherein the strap engaging portions diverge at an angle of between 300 and 80°

6. The patient interface according to any one of claims 1 to 5, wherein the strap engaging portions extend beyond the extreme width of the seal.

7. The patient interface according to claim 6, wherein the strap engaging portions have a distance from the extreme width of the seal to a tip of the strap engaging portion between 10mm and 35mm.

8. The patient interface according to any one of claims 1 to 7, wherein a loop strap extends from the strap engaging portion to secure the interface to the patient.

9. The patient interface according to claim 8, wherein the strap is a hollow elongated tube or a solid elongated tube.

10. The patient interface according to any one of claims 1 to 9, wherein an overall plan form of the seal is parabolic, half elliptical, half oval or U-shaped.

11. The patient interface according to any one of claims 1 to 10, wherein the seal curves about and does not extend over a region of the user's nasal bridge.

12. The patient interface according to any one of claims 1 to 11, wherein the side portions extend completely over the sides of the user's nose.

13. The patient interface according to any one of claims 1 to 12, wherein the side portions extend at least partially over the user's cheeks.

14. The patient interface according to any one of claims 1 to 13, wherein the seal includes an extension to go over the user's mouth.

15. The patient interface according to claim 14, wherein the extension includes an outlet directed to the user's mouth.

16. The patient interface according to any one of claims 1 to 15, wherein the central portion of the seal defines a width of the seal, with the side portions of the seal extending away from lateral ends of the central portion.

17. The patient interface according to any one of claims 1 to 16, wherein the side portions of the seal are substantially parallel to each other and substantially normal to the central portion of the seal.

18. The patient interface according to any one of claims 1 to 17, wherein the mask body is formed of a material more rigid than the seal.

19. The patient interface according to any one of claims 1 to 18, wherein the seal is permanently attached to the mask body.

20. The patient interface according to any one of claims 1 to 19, wherein the seal is permanently attached to the mask body by overmoulding or bonding.

Application 2021201842 Claims

1. A nasal seal for a patient interface:

the seal including a face contacting side and an exterior side, the seal being formed of a soft flexible material, and including a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each side portion extending across a side of the nose,

the face contacting side of the seal being supple to conform under internal pressure to the surfaces of the nose of a wearer, including at the side portions of the seal, to outside surfaces of the sides of the nose,

wherein a peripheral portion of the seal, joining the face contacting side to the exterior side, is supple and allows the interior side of the seal to displace relative to the exterior side.

2. The nasal seal according to claim 1, wherein the seal is inflatable.

3. The nasal seal according to claim 1 or 2, wherein the supple portions of the seal comprise a silicone material with a thickness between 0.05mm and 0.5mm.

4. The nasal seal according to claim 1 or 2, wherein the supple portions of the seal comprise an elastomer with a thickness between 0.1mm and 0.2mm.

5. The nasal seal according to any one of claims 1 to 4, wherein the exterior side of the seal includes regions much stiffer than the supple interior side, the regions extending into the side portions of the seal.

6. The nasal seal according to claim 5, wherein the regions much stiffer than the supple interior side are formed of thicker material than the face contacting side.

7. The nasal seal according to claim 5 or 6, wherein the regions much stiffer than the supple interior side of the seal comprise a silicone material with a thickness between 2mm and 5mm.

8. The nasal seal according to claim 5 or 6, wherein the regions much stiffer than the supple interior side of the seal comprise an elastomer with a thickness between 2mm and 3mm.

9. The nasal seal according to any one of claims 5 to 8, wherein the regions much stiffer than the supple interior side resist outward flexing of the side portions of the seal when the seal is inflated under pressure.

10. The nasal seal according to any one of claims 5 to 9, wherein the regions much stiffer than the supple interior side include a composite material or combination of parts.

11. The nasal seal according to any one of claims 5 to 10, wherein the regions much stiffer than the supple interior side include a reinforcement or a flexible insert of stiff material.

12. The nasal seal according to claim 11, wherein the insert of stiff material is integrated to a mask body.

13. The nasal seal according to any one of claims 1 to 12, wherein the side portions provide resistance to flexing with an effective stiffness of at least 1N force at the end of the regions much stiffer than the supple interior side to flex the side portion through an angle of about 60°.

14. The nasal seal according to any one of claims 1 to 13, wherein the exterior side includes regions having a stiffness corresponding to a silicone material with a thickness between 2mm and 5mm and a Shore A hardness of 40, the regions extending into the side portions of the seal.

15. The nasal seal according to any one of claims 1 to 14, wherein the exterior side of the central portion of the seal includes an opening for passing gases to and from the interior of the seal.

16. The nasal seal according to claim 15, wherein the opening is configured to be fitted to a mask body, or directly to a conduit extending through a mask body.

17. The nasal seal according to claim 15 or 16, wherein the opening includes lips and/or channels to engage with channels and/or lips on the mask body.

18. The nasal seal according to claim 15 or 16, wherein the opening is formed with clip portions, or clip portions are attached to or over-moulded to a perimeter of the opening to facilitate engagement with the mask body.

19. The nasal seal according to any one of claims 15 to 18, wherein the central portion extends above and below the opening, the central portion including regions above and below the opening that are thin and supple.

20. The nasal seal according to any one of claims 15 to 19, wherein above the opening, the central portion includes an outer-facing wall, an inward-facing wall and a perimeter portion, wherein at least the inward-facing wall and the perimeter portion are thin and supple.

21. The nasal seal according to any one of claims 15 to 20, wherein below the opening, the central portion includes an outer wall portion, an inner wall portion and a peripheral portion, wherein at least the inner wall portion and the peripheral portion are thin and supple.

22. The nasal seal according to any one of claims 1 to 21, wherein the side portions of the seal are substantially parallel to each other and substantially normal to the central portion of the seal.

23. The nasal seal according to any one of claims 1 to 22, wherein an overall plan form of the seal is parabolic, half elliptical, half oval or U-shaped.

24. The nasal seal according to any one of claims 1 to 23, wherein the seal curves about and does not extend over the region of the user's nasal bridge.

25. The nasal seal according to any one of claims 1 to 24, wherein the seal has an overall width from outside surface of one side portion to outside surface of the other side portion of between 30mm and 60mm.

26. The nasal seal according to any one of claims 1 to 25, wherein the seal has an overall depth, from the outer surface of the central portion to a line joining the extreme ends of each side portion, between 40mm and 65mm.

27. The nasal seal according to any one of claims 1 to 26 including an extension to go over the user's mouth.

28. The nasal seal according to claim 27, wherein the extension includes an outlet directed to the user's mouth.

29. A patient interface comprising the nasal seal according to any one of claims 1 to 28.

30. The patient interface according to claim 29 including a mask body assembled to the seal, the body being formed of a material more rigid than the seal, and together with the seal forming an enclosure having an inlet opening and a patient outlet opening.

31. The patient interface according to claim 30 further including a swivelling elbow connected to the inlet opening.

32. An assembly comprising the nasal seal according to any one of claims 1 to 28 supported by a mask body, the mask body being formed of a material more rigid than the nasal seal.

33. The assembly according to claim 32, wherein the mask body together with the seal forms an enclosure having an inlet opening and a patient outlet opening.

34. The assembly according to claim 32 or 33, wherein the seal is permanently attached to the mask body.

35. The assembly according to claim 34, wherein the seal is attached by overmoulding or bonding.

Application 2021201843 Claims

1. An assembly for a patient interface, the assembly comprising:

a nasal seal including a face contacting side, the seal being formed of a soft flexible material, and including a central portion to extend across the base of the nose, and a side portion extending from each end of the central portion, each side portion extending across a side of the nose,

the face contacting side of the seal being supple to conform under internal pressure to the surfaces of the nose of a wearer, including, at the side portions of the seal, to outside surfaces of the sides of the nose,

an exterior side of the seal including regions much stiffer than the supple interior side, the regions extending into the side portions of the seal,

the seal includes an extension to go over the user's mouth, and

a mask body assembled to the seal, the mask body formed of a material more rigid than the seal,

and together with the seal forming an enclosure having an inlet opening and a patient outlet opening.

2. The assembly according to claim 1, wherein the seal is inflatable.

3. The assembly according to claim 1 or 2, wherein the extension includes an outlet directed to the user's mouth.

4. The assembly according to any one of claims 1 to 3, wherein the seal is permanently attached to the mask body.

5. The assembly according to claim 4, wherein the seal is attached by overmoulding or bonding.

6. The assembly according to any one of claims 1 to 5, wherein the seal includes overmoulded or bonded rigid plastic barbs configured to clip into correspondingly shaped recesses formed in the mask body and hold the nasal seal in sealing engagement with the mask body.

7. The assembly according to any one of claims 1 to 5, wherein the seal has a periphery that is formed with an overmoulded or bonded rigid plastic looped clip configured to clip to the mask body.

8. The assembly according to any one of claims 1 to 5, wherein the mask body includes a nasal seal engaging portion that engages the exterior side of the seal.

9. The assembly according to any one of claims 1 to 8, wherein the seal comprises an opening and the mask body comprises a seal opening for engaging with the opening of the seal.

10. The assembly according to claim 9, wherein the opening of the seal is in an outwardly facing wall of the central portion of the seal.

11. The assembly according to claim 10, wherein the opening of the seal includes features to engage with complementary features on the mask body.

12. The assembly according to claim 11, wherein the feature on the opening of the seal are lips and/or channels and the complementary features on the mask body are channels and/or lips.

13. The assembly according to any one of claims 1 to 12, wherein the regions much stiffer than the supple interior side include a reinforcement or a flexible insert of stiff material.

14. The assembly according to claim 13, wherein the insert of stiff material is integrated to the mask body.

15. The assembly according to any one of claims 1 to 14, wherein an opening of the seal is commensurate with the extent of the mask body, this extent being commensurate with the general width of the assembly and approximately with the width of the nose of the intended wearer.

16. The assembly according to any one of claims 1 to 15, wherein a region adjacent and including an opening of the seal is much stiffer than the rest of the seal.

17. The assembly according to any one of claims 1 to 16, wherein a region adjacent and including an opening of the seal is formed thicker in the same material than the rest of the seal.

18. The assembly according to any one of claims 1 to 17, wherein a region adjacent and including an opening of the seal is formed of a stiffer material than the rest of the seal.

19. The assembly according to any one of claims 1 to 18, wherein the central portion extends above and below an opening, the central portion including regions above and below the opening that are thin and supple.

20. The assembly according to any one of claims 1 to 19, wherein above an opening, the central portion includes an outer-facing wall, an inward-facing wall and a perimeter portion, wherein at least the inward-facing wall and the perimeter portion are thin and supple.

21. The assembly according to any one of claims 1 to 20, wherein below an opening, the central portion includes an outer wall portion, an inner wall portion and a peripheral portion, wherein at least the inner wall portion and the peripheral portion are thin and supple.

22. The assembly according to any one of claims 1 to 21, wherein the side portions each include an outward face portion and an inward face portion and a peripheral edge portion that joins the inward face portion and the outward face portion.

23. The assembly according to claim 22, wherein the peripheral edge portions of the seal allow the mask body to displace both laterally and vertically relative to axes of the patient's face.

24. The assembly according to any one of claims 1 to 23, wherein the mask body includes at least one strap engaging portion for engaging a loop strap to secure the interface to the patient.

25. The assembly according to claim 24, wherein the central portion of the mask body defines a convex shape generally matching a convex shape of an outwardly facing wall of the seal, with the strap engaging portion extending from a lateral extreme of the central portion, the strap engaging portion extending away from the central portion at an angle outwardly aligned relative to the general convex shape.

26. The assembly according to claim 24 or 25, including at least two strap engaging portions, wherein each strap engaging portion extends laterally away from the inlet opening, from opposite sides of the inlet opening.

27. The assembly according to any one of claims 24 to 26, wherein the strap engaging portion extends away from the exterior side of the seal with an included angle between the strap engaging portion and the exterior side greater than 30°.

28. The assembly according to any one of claims 24 to 27, wherein the strap engaging portion extends beyond the extreme width of the seal.

29. The assembly according to claim 28, wherein the distance from an extreme width of the seal to a tip of the strap engaging portion is between 10mm and 35mm.

30. The assembly according to any one of claims 1 to 29, wherein the mask body includes a socket for connecting with a supply conduit.

31. The assembly according to any one of claims 1 to 30, wherein the mask body is made from a plastics material.

32. The assembly according to claim 31, wherein the mask body is made from polycarbonate or silicone

33. The assembly according to any one of claims 1 to 32, wherein the mask body includes small apertures as part of a gas washout vent.

34. The assembly according to any one of claims 1 to 33, wherein the regions much stiffer than the supple interior side as well as the supple interior side comprise a silicone material, and/or comprise a neoprene material.

35. The assembly according to any one of claims 1 to 34, wherein the regions much stiffer than the supple interior side and the supple interior side are formed in the same material.

36. The assembly according to any one of claims 1 to 35, wherein the regions much stiffer than the supple interior side are formed thicker in the same material as the rest of the seal.

37. The assembly according to claim 36, wherein the regions much stiffer than the supple interior side taper in thickness to reach the thickness of the interior side.

38. The assembly according to any one of claims 1 to 5, wherein the seal comprises an opening in an outwardly facing wall of the central portion of the seal including features to engage with complementary features on the mask body, and the mask body comprises a seal opening for engaging with the opening of the seal, wherein the feature on the opening of the seal are lips and/or channels and the complementary features on the mask body are channels and/or lips, and wherein below the opening, the central portion includes an outer wall portion, an inner wall portion and a peripheral portion, at least the inner wall portion and the peripheral portion being thin and supple.

39. The assembly according to any one of claims 1 to 5, wherein the seal comprises an opening in an outwardly facing wall of the central portion of the seal including features to engage with complementary features on the mask body, and the mask body comprises a seal opening for engaging with the opening of the seal, wherein the feature on the opening of the seal are lips and/or channels and the complementary features on the mask body are channels and/or lips, and wherein the regions much stiffer than the supple interior side are formed thicker in the same material as the rest of the seal and taper in thickness to reach the thickness of the interior side.

40. The assembly according to any one of claims 1 to 5, wherein the seal comprises an opening in an outwardly facing wall of the central portion of the seal including features to engage with complementary features on the mask body, and the mask body comprises a seal opening for engaging with the opening of the seal, wherein the feature on the opening of the seal are lips and/or channels and the complementary features on the mask body are channels and/or lips, wherein below the opening, the central portion includes an outer wall portion, an inner wall portion and a peripheral portion, at least the inner wall portion and the peripheral portion being thin and supple, and wherein the regions much stiffer than the supple interior side are formed thicker in the same material as the rest of the seal and taper in thickness to reach the thickness of the interior side.

41. A patient interface comprising the assembly according to any one of claims 1 to 40, and a strap extending from the assembly in a loop, the strap departing a first portion of the assembly at one end and a second portion of the assembly at its other end.

42. The patient interface according to claim 41, wherein the strap has a stiffness less than 2N per 100mm extension from a relaxed condition.