COMMONWEALTH OF AUSTRALIA

Patents Act 1990

IN THE MATTER OF Australian patent application 2009221630 in the name of RESMED LIMITED

AND

IN THE MATTER OF Opposition thereto by FISHER & PAYKEL HEALTHCARE LIMITED

STATUTORY DECLARATION

I, Alistair Edwin McAuley, consultant, of Rotorua, New Zealand do solemnly and sincerely declare that:

1. **Background**

1.1 I am a medical device consultant, including in relation to devices for the treatment of obstructive sleep apnea (OSA). I am the sole director of the company Medlands Consulting Limited (Medlands).

1.2 I currently work as a consultant to the CEO of Airway Management, a company that produces and sells products for the treatment of sleep apnea. In my current role I do design work, marketing and intellectual property (IP) analysis. The main focus of my role currently is product design and upgrades, and finding buyers for the company's products and ultimately the company's assets.

1.3 I am a part owner and director of a distribution business Airway Management Asia Pacific, distributing Airway Management products, and other companies' products, in New Zealand and Australia. These products are all in the OSA field and include an oral appliance, a CPAP interface, CPAP machines and other accessories. I travel in the market making sales and training calls and attended the Australasian Sleep Association tradeshow in 2014, where we exhibited our products.

1.4 I also do some consulting with Auckland University of Technology, around the commercialisation of its IP, in the OSA field.

1.5 I also consult to Human Design Medical (HDM), a United States based medical device company. That work involves giving them advice on product design, testing, manufacturing and regulatory requirements.

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1.6 I graduated with a Bachelor of Technology degree, with honours, in engineering and automation from Massey University in 1998 (my final year of study at Massey was 1997).

1.7 I started my career with Fisher & Paykel Healthcare Limited (FPH) in 1997 and started working in the company's sleep apnea treatment business in 1998.

1.8 I worked for FPH for 14 years. From 1998 I was in the new mask development team. FPH was producing CPAP (continuous positive air pressure) devices, but needed an interface to be sold with them (an interface is the part of the device for treating sleep apnea which connects the CPAP to the patient, for example, a mask).

1.9 In 2000, I was made the head of that team, where I stayed until 2010. I then spent two years as the Business Development Manager for sleep apnea. During my time at FPH and with Airway Management I have been involved extensively in the intellectual property management area. This includes conducting freedom to operate searches or reviewing them, filing new inventions and helping to respond to examiners' responses. I have filed over 75 United States patent applications as an inventor, of which 45 have been granted. All the applications have been related to the OSA field, mostly interfaces with some related to CPAP and CPAP humidification. These patients have been cited by 478 other patent applications due to their relevance in the OSA device field.

1.10 In 2011, I left FPH to set up a company that operated as a joint venture with a United States company, Airway Management (Airway Technologies). My involvement with Airway Management began when Airway Management had initial discussions about a joint venture with Medlands. The idea behind the joint venture was that we would design and tool a nasal pillow mask, and design an oral appliance. As part of this, it was agreed that I would go over to the United States for six months to help Airway Management get their new products into the market. The company's main product line was oral appliances to treat OSA (devices that fit inside the patient's mouth, to adjust how the jaw sits). I was also assisting with Airway Management getting FDA and ISO 13485 approval for its devices. For one year I worked on research and development working very closely with Airway Management. We developed a CPAP interface there.

1.11 After about a year of the joint venture, Airway Management wanted help integrating its products into the market and into Europe, so I became president of the company for a year and a half. The CEO decided to appoint me as president to allow me to manage the company, integrating the new products and upgrading the quality systems to achieve ISO 13485 compliance. The owner and CEO of Airway Management was part time so did not have daily involvement in the running of the company. I was the most experienced person in the company, from a medical device design and manufacturing point of view. My president role was the equivalent of being a general manager, with all functions reporting to me. I reported to the CEO.

1.12 A copy of my curriculum vitae as at February 2015 is attached as exhibit AM-1.

1.13 I have read the Federal Court of Australia Practice Notes CM7 titled 'Expert witnesses and proceedings in the Federal Court of Australia'. I understand what is expected of me as an expert witness and I confirm I give the following evidence in accordance with Federal Court guidelines.

1.14 In particular the issues I address and the evidence I give in this declaration are within my areas of expertise. I realise that my overriding duty is to assist the Commissioner impartially on relevant matters within my areas of expertise and I am not an advocate for FPH who has engaged me as a witness.

1.15 I am being paid within my standard range of remuneration for consulting work, for my time spent in preparing this evidence and attending at the hearing if necessary.

1.16 The evidence I give is my own assessment and opinion. My opinions are wholly or substantially based on my specialised knowledge.

1.17 AJ Park asked me to explain how interfaces are generally developed within the industry, and the considerations and features that go into the development of an interface. Unless stated otherwise, the points I make in this declaration reflect the position as at February 2008. I also discuss some examples of headgear. My discussion of headgear is to reflect the position as at January 2003, unless I state otherwise.

1.18 Where I refer to examples of masks or patents, I confirm that these are masks I was aware of (which the patents record details of), prior to February 2008, when I was working in this area. I have done some limited patent searching in order to refresh my recollection of the masks and patents I was aware of prior to that date. I restricted this searching to patents before 2008.

1.19 To assist, I have prepared a document that details common terms and definitions in this area. I attach this as exhibit AM-2.

2. The interface market

2.1 The market for CPAP treatment (CPAP machines and interfaces) is a global market. There is no real variation in the products available throughout the market, just the size of the distribution in different areas.

2.2 The major players in the market are ResMed (who has around 50% of the market), Philips (who acquired Respironics, a significant manufacturer of CPAP machines and interfaces, around seven years ago), and FPH, who are large, but distinctly smaller than the other two big players. There is then a second tier, of companies who have around a 1-2% market share each, these include Breas and DeVilbiss Healthcare. And a third tier which would encompass less than 5% of the total market between them. Airway Management sits in this third tier.

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2.3 In the 2014 calendar year, ResMed had revenue of US$1.616 billion. I estimate this represents around 50% of the total OSA market, from a manufacturer's point of view. I estimate Philips had revenue from CPAP machines and interfaces (Sleep Therapy business, excluding hospital and other non CPAP related respiratory business) of around US$1.2 billion and this represents around 38% of the market. I estimate (based on reported results and extrapolations) that FPH had revenue of around US$210 million from CPAP machines and interfaces and this represents around 6.5% of the market. The remainder of the market has a revenue of around US$160 million, which is around 5% of the market, once again this is an estimate as not all of these companies report revenue.

2.4 My assessment of the Philips market share is an estimate. When Philips bought Respironics it stopped publically reporting its OSA market results separately. At the time Philips bought Respironics it was around 50% of the market. I estimate it is now more like 38%, being stronger in CPAP and weaker in interfaces.

2.5 ResMed primarily operates in the OSA business. It publically reports its results, and reports on the CPAP machine side of its business and the interface side of its business separately. FPH also reports its OSA financial information.

2.6 Philips is relatively strong in CPAP machine market, however its masks are regarded as not as good as ResMed or FPH masks. I estimate that they have a lesser share of the mask market than they have in the CPAP market. Philips, or Respironics as it was then, was very strong in the 1990s because they were an early player in the market. But ResMed and FPH have since taken a lot of market share from Philips, particularly in the interface market. There is a feeling that Philips masks were overly complex and consumers did not rate them as highly in areas of comfort and leak performance. ResMed and FPH are stronger in their interface business than CPAP machine business. They would both have a greater market share in the interface business than the CPAP side, although ResMed's CPAP revenue is higher that its interface revenue as the CPAP market is larger. It is common for consumers to have a CPAP machine supplied by one company and an interface supplied by another. For example, it would be quite common for a consumer to have a Philips CPAP machine used with a ResMed interface.

3. Knowledge of the market

3.1 From my experience, people involved in the development of interfaces need to have a knowledge of the market. At FPH, the design team would spend time in the market, at trade shows, and with sales reps visiting sleep labs, doctors' offices and CPAP dealers. This enabled FPH to get feedback on the products and develop products that best meet the users' needs.

3.2 The New Zealand market, and to some extent the Australian market is very small and as there is no need to develop interfaces specifically for New Zealand or Australian

needs it is important to visit the larger markets of North America and Europe regularly to gain feedback from the key markets. Furthermore, as the New Zealand market is so small even if there were some specific needs identified it would most likely be uneconomical for companies to develop specific products for it. Products are developed for the market globally, but developers do focus to some degree on the North American market, because it is around 50% of the market, and insurers' have particular requirements there. For example, insurance may provide for a replacement seal every three months. Therefore, United States dealers are likely to prefer masks that have a seal that is able to be replaced. Because of this, developers would try to develop masks with a replaceable seal.

3.3 While with FPH, I travelled several times a year to major trade shows, conferences, and sales meetings. FPH would also visit overseas component manufacturers, such as tooling suppliers or headgear fabricators such as Acumed Technologies in the United States, a global leader in the design and manufacture of headgear for CPAP masks. When I was managing the FPH interface R&D team I would usually take a two week trip to the United States once or twice a year and a three week trip to Europe every couple of years. The marketing team would also travel regularly in the same manner. I was also in email and phone communication, almost every week, with the marketing manager for FPH in the United States, he would give us feedback on the market, specifically about any performance issues with our products and the key competitors.

3.4 Of these United States trips one week would be spent at a trade show. The following are examples of these trade shows:

3.4.1 APSS (Associated Professional Sleep Societies—a joint meeting between the American Academy of Sleep Medicine and the Sleep Research Society) conference. This is a show where clinicians, sleep technicians and physicians attend. At the APSS conference there would be presentation of clinical papers and research in the sleep field, as well as a trade show area where manufacturers would display their products and highlight new products. At the APSS I have seen sleep lab staff from New Zealand, as well as sleep physicians from New Zealand and Australia. They would attend the clinical sessions and visit the manufacturers' booths to see the latest products on offer. This is relevant to them as manufacturers release the same products in the United States as they do in Australia and New Zealand. I have also visited these people in New Zealand and Australia, at their sleep labs or offices. I have also seen independent medical distributors from Australia attending this show, as they source many of their products from United States manufacturers exhibiting at these types of shows.

A-15

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