



Submission to ACIP - Patentable Subject Matter Options Paper
November 2009

In this submission, we provide a background on ResMed's experiences of the Patent system to date. We discuss the possible implications of changes to Patentable subject matter to ResMed and to other medical technology businesses in Australia. Finally we make some brief comments on the Options proposed.

In general we think the patent system can enhance the widespread adoption of "any new and ingenious contrivances"¹ rewarding the application of skill, craft and cleverness. We consider that businesses or development proposals with a portfolio of valid relevant intellectual property rights make a more attractive investment. The effect of making certain "contrivances" unpatentable may be to make it less attractive for businesses to conduct research and development in that area. Intellectual property rights provide a mechanism to create a more tangible tradable asset out of research and development. Furthermore excluding certain technologies from patentability may lead to a greater reliance on confidentiality.

ResMed

ResMed is a developer and manufacturer of medical devices for treating a range of respiratory conditions. Two major product lines are masks and Positive Airway Pressure (PAP) devices. This year is our twentieth year of operation. In the financial year ending 30 June 2009 net revenue was \$US920 million and the European and American markets represented approximately 92% of ResMed's sales. ResMed sales in the Asia-Pacific region, including Australia, Hong Kong, Japan, New Zealand, Singapore, China and India and the rest of the world accounted for approximately 8% of ResMed sales². ResMed has approximately 2,900 employees worldwide.

We believe that continued product development and innovation are key factors to our ongoing success. Approximately 11% of our employees are devoted to research and development activities. In fiscal year 2009, we invested \$63.1 million, or 7% of our revenues, in research and development³.

The markets for our products are highly competitive. We believe that the principal competitive factors in all of our markets are product features, reliability and price. Customer support, reputation and efficient distribution are also important factors.

We compete on a market-by-market basis with various companies, some of which have greater financial, research, manufacturing and marketing resources than us. In the United States, our principal market, Philips BV, who acquired Respironics Inc., a previous competitor; DeVilbiss, a division of Sunrise Medical Inc.; Nellcor Puritan Bennett, a division of Covidien Ltd.; and Fisher & Paykel Healthcare Corporation Limited are the primary competitors for our products. Our principal

¹ Mola L (2000) *The Silk Industry of Renaissance Venice*, Johns Hopkins University Press, Baltimore. Quoted from Google books.

² ResMed 2009 Annual Report

³ *ibid*

European competitors are also Philips, DeVilbiss, and Nellcor Puritan Bennett, as well as regional European manufacturers.

ResMed owns or licenses approximately 200 issued US utility patents, as well as corresponding international patents. We also have a portfolio of pending applications, including approximately 320 pending US utility patent applications. Furthermore we have a portfolio of approximately 200 US design patents (also known as design registrations).

ResMed has been involved in Intellectual Property disputes both as a plaintiff and defendant.

We have encountered a number of knock-offs of both our mask and PAP devices. In these encounters our patent portfolio has been a basis of negotiating settlement.

Most of our competitors have patent portfolios. We review competitor patents during ResMed product development. We do not include features in our products that are the subject of known valid third party intellectual property rights. Upon expiration of a competitor patent right, we would consider that patent to be no longer an impediment to ResMed's use of that technology.

We maintain a library of expired patent art and use it to help us evaluate the scope of existing patent claims.

In short, we use the patent system to reduce copying of our inventions during the term of our patents, we do not incorporate competitor patented features during the term of their patents, and we use our knowledge of expired patents to assist us in freedom to operate evaluations.

The issue of contentious patentable subject matter is relevant to us in two areas: methods of medical treatment *per se*, and processes implemented in computer software. Another area of current controversy with respect to patentable subject matter relates to genetic technologies however ResMed does not currently have products, research or patents in this area.

Methods of medical treatment

As a producer of medical devices, patents on methods of medical treatment are of interest to us. This subject matter is excluded from patentability in Europe but allowed in the United States of America and Australia.

The patentability of methods of medical treatment in Australia was one of the issues in dispute when as ResCare, we were involved in litigation⁴. At that time, the issue was very important to our business. Since ResMed is now a much larger global company, if Australian Patent law were changed to eliminate patents on methods of medical treatment, it would probably have little impact on ResMed today.

However the patentability of methods of medical treatment in Australia may assist small start-up

⁴ Anaesthetic Supplies Pty Limited v Rescare Limited [1994] FCA 1065; (1994) 122 ALR 141 (1994) Aipc 91-076 (5 May 1994)

medical device companies to become established in Australia, before launching onto the global market. Removing patentability of methods of medical treatment in Australia may mean that initial commercialisation of Australian technology will take place in other countries such as the United States.

Processes implemented in software

Questions of patentable subject matter are also of relevance to us in relation to the control algorithms embedded in our automatic devices. Our treatment algorithms are a core technical strength. Such algorithms enhance detection, monitoring, diagnosis and treatment of a range of respiratory conditions such as Cheyne-Stokes respiration.

We do not seek patents on all of our algorithm inventions, choosing instead to keep some confidential. We do this to reduce the risk of such inventions being copied.

One editorial⁵ has noted that “*the marketplace [has] made medical equipment manufacturers reluctant to divulge detailed descriptions of the technology used in their devices. ... medical devices that collect, filter and analyze data, providing only the processed version to the clinician, or those that interpose their own judgement in diagnosing a condition or treating a patient must be subject to much more investigation before we can fully trust their functionality.*”

As computer software becomes more prevalent in medical devices in the future, it may be making more complex decisions about diagnosis and treatment. In an environment where such software may be readily copied, businesses may prefer to rely on confidentiality whenever possible.

We suggest that if businesses believed that their software algorithms would not be copied, they may be more likely to reveal them.

ResMed faces a range of practical matters in relation to patentable subject matter including different laws in different jurisdictions, uncertainties, costs and delays each of which influence our decisions as to whether to seek patents and the form in which they take.

Even though we may be bringing the same technology to every country, ResMed must engage experts in every jurisdiction to ensure that its patent applications conform to local laws. This adds to the expense of patenting, and ultimately to the cost of producing product.

Where issues of law may be uncertain, ResMed must decide whether it is worth pursuing a case through the courts simply to establish whether a given technology is *per se* patentable.

Of all jurisdictions, changes to the subject matter patentable in ResMed's major markets of the US and Europe would probably have the most significant impact on our business and our patent prosecution strategy.

5 Brown (2006) Autotitrating CPAP - How shall we judge safety and efficacy of a “Black Box”?, Chest J 130.

Brief comments on Options

Part 1: Economic test

Each of the options of Retain, Clarify, Replace, Delete and Enhance has strengths and weaknesses. We believe the Options Paper provides a useful summary of these strengths and weaknesses.

Uncertainties and unpredictability are challenges for many areas of law, including the Patent system. The sources of these challenges can be from existing law, and from making changes to the law. Applicants should be in a position to make an informed choice as to whether to seek a patent, or to keep their inventions confidential.

We favour an approach that does not exclude any particular field of technology. We believe concerns about access to technology may be addressed with compulsory licences, for example via existing Section 133 of the Patents Act. Furthermore, Patent pools offering licences on a fair, reasonable, non-discriminatory basis may also provide a mechanism to address concerns about access to essential technologies.

Part 2: Social Filter

Uncertainties in the nature of a social filter and how it could be applied make it difficult to comment on these options. There is a risk that such filters may exclude beneficial areas of technology and research.

Legislative bodies are already in the position to make laws banning or regulating any particular product. Furthermore the public can choose not to purchase products they deem immoral.

We note that copyright subsists in works without regard to the perceived morality of the work.

Part 3: Enhancements

Patents in jurisdictions such as the United States, Europe, Japan and China are very economically valuable to Australian inventors. Conformity with Patent law in those jurisdictions, or cooperation between Patent Offices to allow examination in Australia according to the laws of one or more of those jurisdictions would allow Australian inventors to obtain quality international standard patents via their local patent office. This would be a major practical enhancement.