MedTech IP

Lessons and strategies for success

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Introduction

IP can be a powerful tool for almost any business, but not all industries are the same, so not all strategies should be the same.

In this eBook we look at IP-related issues faced by those seeking success in the MedTech field and we identify opportunities and solutions based upon the experiences of those who have faced them before.

Each chapter contains a summary of key points for the topic discussed, followed by one or more case studies giving more details on the topic.

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1. Keep innovating: The remarkable story of ResMed

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1. Keep innovating: The remarkable story of ResMed

Nobody can ever be 100% certain about the validity of any individual patent. The reason is simple; no patent search can ever prove that someone else did not create the same invention previously.

It is therefore important to keep innovating, and to continue to patent new technology as it arises, so you have a back-up plan if any individual patent fails.

An evolving armoury of IP rights can also enable you to adapt to changing markets and even enable you to define markets.

So, building a constantly evolving portfolio of patents isn't just a defensive measure – it can be a way to define opportunity and foster growth.

Let us see how ResMed went about this in rather spectacular fashion…

A Continuous Positive Airway Pressure (CPAP) machine provides CPAP to a patient via a face mask. This prevents collapse of the upper airway, and CPAP therapy is therefore highly effective for managing obstructive sleep apnea, among other conditions.

You may already know that ResMed, established in Australia in 1989, is the world's largest manufacturer of CPAP devices, employing over 10,000 people worldwide, operating in more than 140 countries, and with a revenue of US$4.2 billion in fiscal year 2023.

You may also know that ResMed has filed over 10,000 patent applications.

What you may not know is that in 1993, just 4 years after ResMed was established in Australia, three judges of the Australian Federal Court completely revoked ResMed's foundational patent for the invention of the CPAP machine.

How did this company, which had its foundational patent completely revoked, go on to become the world's largest manufacturer of CPAP devices? To answer this question we need to look in a little more detail at the story of the CPAP machine.

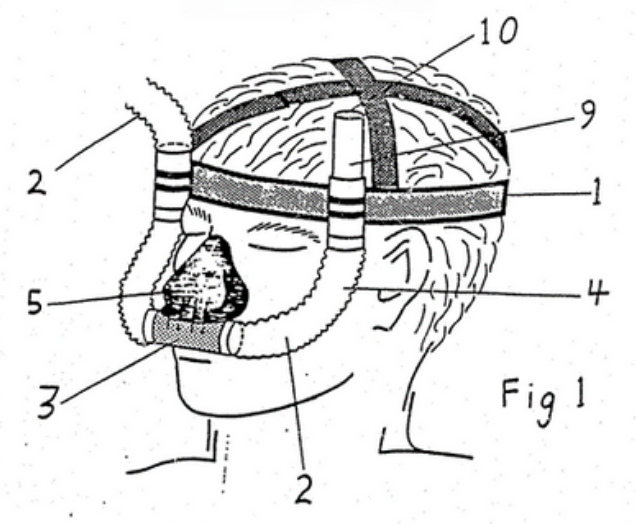
The CPAP industry is now a huge MedTech industry. According to a report from the US Securities and Exchange Commission, more than 8 million CPAP interfaces are sold annually in the US, with another 2.5 million globally. There are also an estimated 80 million people with undiagnosed sleep apnea.

1. Keep innovating: The remarkable story of ResMed

How did this multi-billion dollar industry begin?

The CPAP machine was invented in Australia in 1980 by Colin Sullivan, an Australian physician and professor, who was determined to patent his invention, against the odds. Sullivan originally sought assistance from his university's Business Liaison Office for obtaining patent protection for his invention. This request was declined, and Sullivan then used his own resources to patent a "Device for treating snoring sickness" that issued as Australian Patent AU 560,360.

Figure 1 of the original patent is shown on the right, and illustrates the fundamental concept of the CPAP machine. The patent states that, "the patient will have administered to the nasal passages air of slightly increased pressure sufficient to maintain the nasal passages open throughout the breathing cycle."



A collaboration between Sullivan and a colleague led to a further patented invention, namely the delay timer patent (PCT/AU88/00, 8 Sep 1987) issuing as US patent 5,199,424 on 6 April 1993. This was achieved by providing an initial low pressure, to allow the patient to go to sleep, followed by gradually increasing the pressure to the required level, over a selectable time period.

A further patented invention used a microphone to detect when snoring occurred, and used this information to increase the air pressure only when needed to prevent an apnea from developing. This was based on the realisation that most apneas are preceded by snoring. The invention provided the patient with better sleep, and lower average delivered pressure during the night, thus increasing compliance with the therapy.

In 1989 ResMed was established in Australia to develop Colin Sullivan's invention of the CPAP machine.

The key thing was that, after filing a patent application for the idea of a CPAP machine, innovation had continued, and the company now owned a number of patents relating to

further developments of the CPAP machine. So when in 1993 the Australian Federal Court unfortunately revoked the original patent, all was not lost. ResMed then initiated an action alleging infringement of ResMed's surviving patents.

Fortunately, ResMed had not simply relied on the original patent, but had further patents which could be asserted against alleged infringers.

According to the publication Medtech Dive, ResMed is now the largest manufacturer of CPAP and bilevel positive airway pressure devices in the world by market share. ResMed relocated to San Diego, California in 1990, and is now a medical equipment company which provides cloud-connectable medical devices for the treatment of sleep apnea (such as CPAP devices and masks), chronic obstructive pulmonary disease (COPD), and other respiratory conditions.

The story of how Colin Sullivan's invention of the CPAP machine in 1980 led to a multi-billion dollar industry is a remarkable story of success. Clearly patents have been central to this success story, starting with Colin Sullivan's original patent mentioned above, which he financed himself. The company was successful because in the early days the company did not simply rely on the original patent, but continued innovating and patenting new developments.

2. Don't take "No" for an answer: Surgery and diagnosis

Julian Asquith

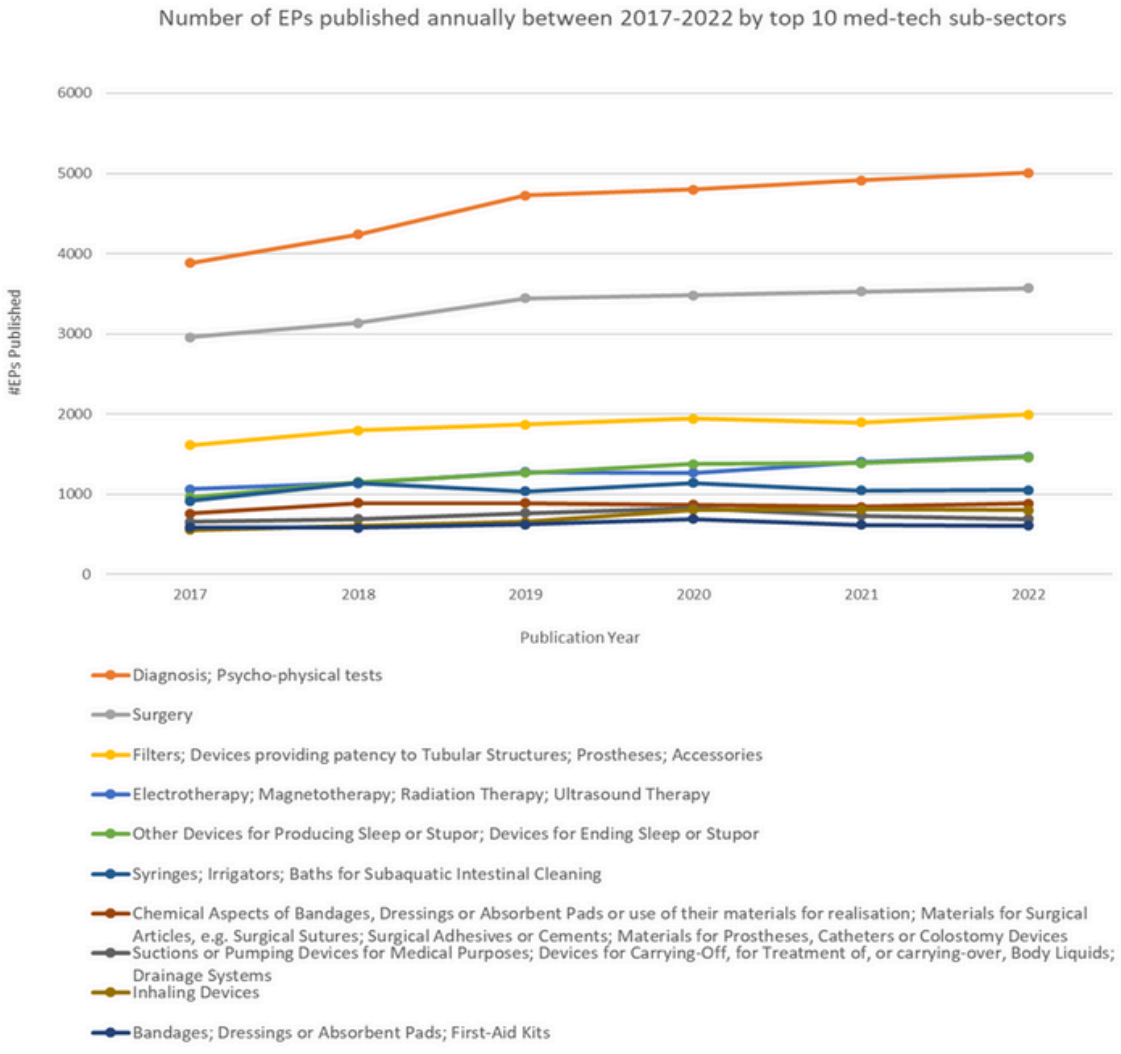
2. Don't take "No" for an answer: Surgery and diagnosis

The European Patent Convention (EPC) decrees that European patents shall not be granted in respect of:

"methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body ..."

With some variations, similar provisions apply in other jurisdictions all over the world. This is often understood to be a significant barrier to large swathes of patent protection within MedTech circles, but is it really a barrier?

It is important to understand that this exclusion relates only to certain methods, and not to medical devices and products. In fact, there are actually more European patent applications published in the areas of surgery and diagnosis than in any other area of MedTech. This is illustrated in the following graph, which shows the number of published European patent applications over recent years for the top 10 sub-sectors in the MedTech industry.



2. Don't take "No" for an answer: Surgery and diagnosis

As you can see in the graph: not only are areas of surgery and diagnosis at the top of the charts, but the number of patent applications in these areas have actually been increasing over recent years.

Let’s see how all this was made possible …

Born on 29 July 1898 into a Polish-Jewish Orthodox family, Isidor Isaac Rabi was a close friend of Robert Oppenheimer, the well-known American physicist responsible for developing the first atomic bomb during World War II. In the 2023 film Oppenheimer, Dr Rabi can be seen testifying on behalf of Oppenheimer at the Atomic Energy Commission's controversial security hearing in 1954 that led to Oppenheimer being stripped of his security clearance.

After growing up in New York and completing his PhD, in 1927 Isidor Rabi headed to Europe where he spent two years immersing himself in the new field of quantum mechanics, working with such giants as Bohr, Pauli, and Heisenberg. He gained a reputation for reinventing experiments to seek insights that brought him, he wrote, “nearer to God.” “You’re wrestling with a champ,” he would tell his physics students. “You’re trying to find out how God made the world, just like Jacob wrestling with the angel.”

Isidor Rabi returned to the US, and in 1937 he predicted that atomic nuclei aligned by a magnetic field and subject to a pulse of radio waves would absorb this pulse and flip their spin. When their spin flipped back they would re-emit the pulse, which experimenters could detect. Importantly, different kinds of materials absorbed and re-emitted pulses at different frequencies, thus allowing scientists to distinguish between materials, even within solids.

Isidor had discovered nuclear magnetic resonance (NMR), for which he won the 1944 Nobel Prize, and this discovery formed the basis of magnetic resonance imaging (MRI), which identifies atoms by how they behave in magnetic fields and produces very clear images within the body.

After Isidor Rabi's ground-breaking discovery, there have been many subsequent inventions relating to MRI imaging, leading to many patents and at least a further four

2. Don't take "No" for an answer: Surgery and diagnosis

Nobel prizes. Here we look at one such invention relating to the injection of a magnetic contrast agent, which will teach us something about patent law relating to surgery and diagnosis.

In July 1997 Martin Prince from Michigan filed International Patent Application No. PCT/US96/20338 for a "Method and apparatus for magnetic resonance imaging of arteries using a magnetic contrast agent." Little known to Prince at the time, his application was to help shape the course of patent law in this area, but he was also in for a long patent journey.

Prince was successful in obtaining grant of his patent application in 22 March 2000. The application was granted as European Patent No 0 812 151. However, that was not the end of the story. In Europe, granted patents can be opposed within 9 months of grant, and a notice of opposition was filed against Prince's patent by Koninklijke Philips Electronics N.V. on 19 December 2000, just three days before the 9 month deadline.

Unfortunately for Prince, the opposition was successful. In its decision revoking the patent, dispatched on 11 June 2002, the opposition division held that the subject-matter of the claims 1-11 of the granted patent was excluded from patentability because it constituted a diagnostic method practised on the human or animal body and, moreover, included a step of treatment of the human or animal body by surgery.

As noted above, the European Patent Convention (EPC) does not allow patents for certain methods practised on the human or animal body, but the exclusion applies only to methods, and not to medical devices and products.

Returning to our story, Prince appealed against the decision of the opposition division.

However, Prince's bad luck had not yet run out. It just so happened that, at the time of Prince's appeal, the President of the European Patent Office (EPO) referred a point of law to the Enlarged Board of Appeal (EBA) of the EPO concerning very similar issues as were raised by Prince's case. Following this a further similar point of law was referred to

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the EBA. Such referrals to the EBA are rare, and Prince was unlucky to have two such referrals which were both relevant to his patent application. The result of these two referrals was to delay Prince's own appeal by over , before oral proceedings were summoned on his appeal in 2010. Clearly, Prince had staying power, as it was by now 13 years since the filing of his original PCT application in 1997.

The EBA at the European Patent Office decides on points of law of fundamental importance, and the points of law referred by the EPO President resulted in two key decisions, G 1/04 concerning diagnostic methods practised on the human or animal body, and G 1/07 concerning methods for treatment of the human or animal body by surgery.

Prince was, on the one hand, unlucky that these decisions of the EBA caused significant delay to his own appeal, but on the other hand lucky that these decisions of the EBA were helpful to his appeal, as we shall see.

In its opinion for G 1/04 the EBA stated that the method steps to be carried out when making a diagnosis include four key steps:

(i) the examination phase involving the collection of data,
(ii) the comparison of these data with standard values,
(iii) the finding of any significant deviation, i.e. a symptom, during the comparison, and
(iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical decision phase.

The EBA concluded that the diagnostic methods referred to in the exclusion cited above "include the method step related to the deductive medical or veterinary decision phase, i.e. the diagnosis stricto sensu, representing a purely intellectual exercise". The EBA concluded that, in order for a diagnostic method to be excluded from patentability, the method needed to include, "the feature pertaining to the diagnosis for curative purposes as a purely intellectual exercise representing the deductive medical or veterinary decision phase", as well as the preceding steps.

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In simplified terms, claim 1 of Prince's granted patent included the following steps:

"A method of imaging an artery in a region of interest in a patient using magnetic resonance imaging and a magnetic resonance contrast agent, the method containing the steps of:

injecting the magnetic resonance contrast agent into a vein remote from the artery;

monitoring the region of interest by using a series of magnetic resonance radio frequency pulses ... ;

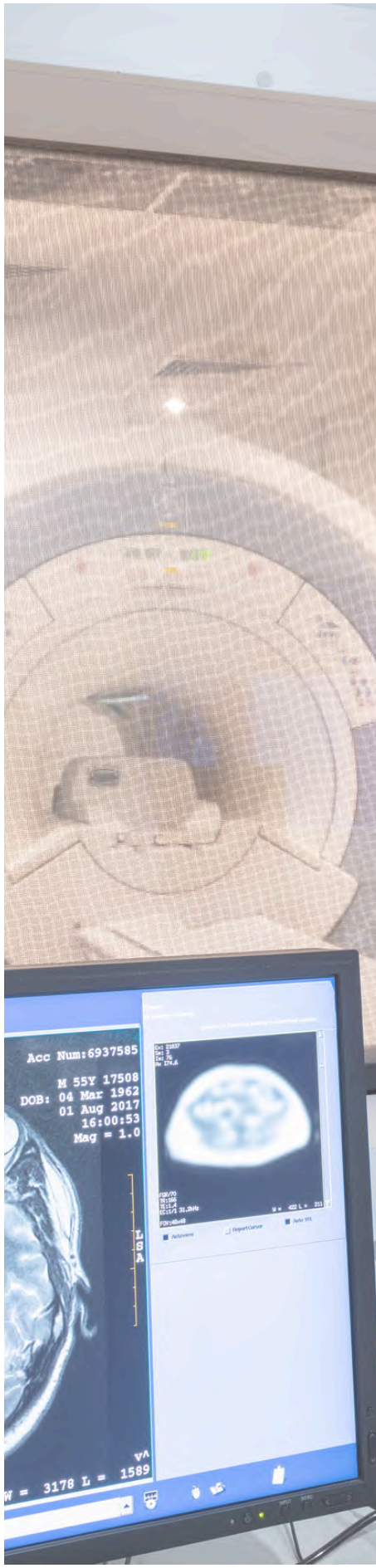
detecting the arrival of the contrast agent in the region of interest ....;

generating an imaging initiation signal after detecting the arrival of the contrast agent in the region of interest;

collecting magnetic resonance image data in a magnetic resonance imaging sequence in response to the imaging initiation signal, ... and

constructing an image of said artery, using the magnetic resonance image data, wherein the artery appears distinct from the adjacent veins and background tissue.

You will notice when reading this claim that it contains no step of performing a diagnosis as a result of the images obtained. In the words of the EBA in decision G 1/04, the claim does not include the "deductive medical decision phase", i.e. step 4 in the four key steps listed above.



2. Don't take "No" for an answer: Surgery and diagnosis

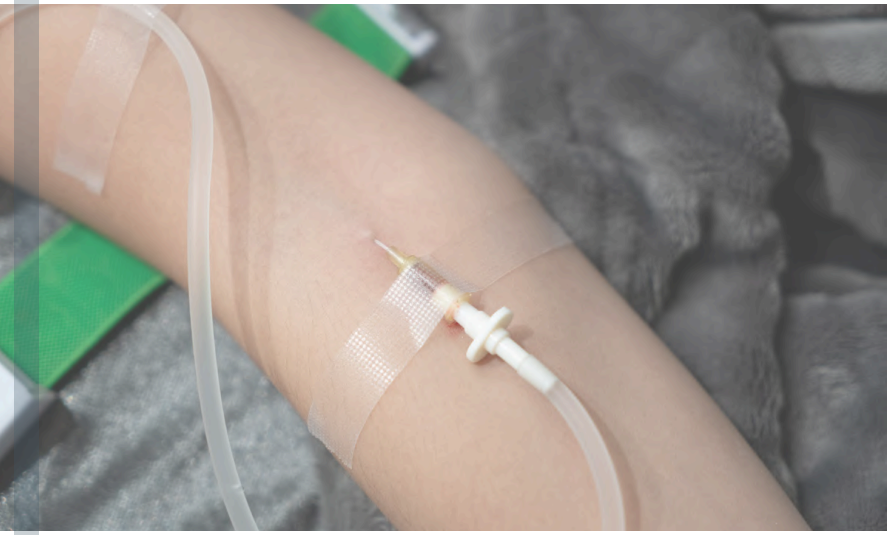
The "diagnosis stricto sensu" is missing. Rather, the claim includes only the preceding steps of gathering information which are constitutive for making the diagnosis (i.e. "monitoring ..., detecting ..., generating ..., collecting ..., constructing ...").

The appeal board had made Prince wait for decision G 1/04 of the EBA, but the wait had paid off. Prince was over the first hurdle. His method was not, after all, a diagnostic method.

However, another hurdle remained for Prince. The opposition division had revoked Prince's patent on another ground, namely that the method included a step of treatment of the human or animal body by surgery. Recall that Prince's method included the step of injecting the magnetic resonance contrast agent into a vein. Was this step of injecting sufficient to amount to a form of "surgery", as the opposition division had held?

Here, the delay in Prince's appeal again paid off. Prince benefitted from decision G 1/07 of the EBA. In that decision, the EBA held that, "Methods for retrieving patient data useful for diagnosis may require administering an agent to the patient, potentially by an invasive step like by injection, in order to yield results or at least they yield better results when using such a step. Considering this technical reality, excluding from patentability also such methods as make use of in principle safe routine techniques, even when of invasive nature, appears to go beyond the purpose of the exclusion of treatments by surgery from patentability in the interest of public health."

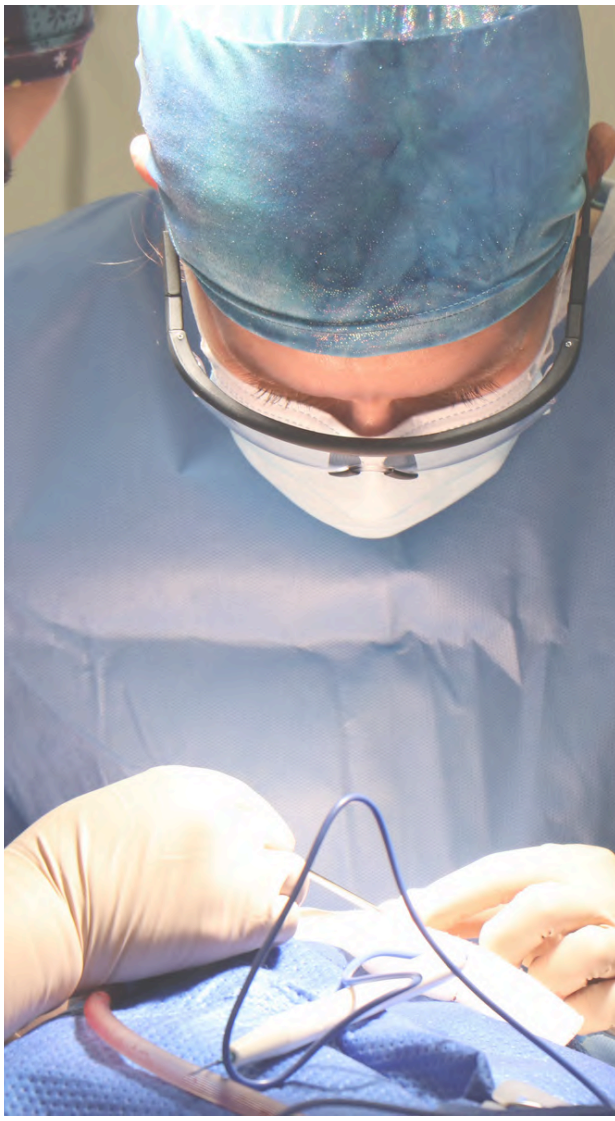
The EBA also consistently argued for a narrow construction of the exclusion from patentability, stating, "a narrower understanding of what constitutes by its nature a "treatment by surgery" ... is required."



Following this guidance, in Prince's case the appeal board held that:

"an intravenous injection can today be delegated by a physician to a qualified paramedical professional. This gives an indirect hint at the fact that such an injection may be considered as representing a minor

routine intervention which does not imply substantial health risks when carried out with the required care and skill. It thus follows that the step of intravenously injecting a contrast agent would be ruled out from the scope of the application of the exclusion clause."



Thus, nearly 14 years after his initial filing date, and nearly 15 years after his priority date, Prince's patent was finally maintained as granted by the appeal board.

For completeness, we note that the exclusion relating to surgery relates to the nature of the treatment rather than its purpose. Therefore methods of treatment by surgery for cosmetic purposes are excluded from patentability, as well as for therapeutic purposes. The reason for this exclusion from patentability is to allow surgeons to perform surgical methods without worrying about whether their surgery may infringe a patent.

Prince's case is instructive because it teaches us something about the limits of the exclusions relating to surgical methods and diagnosis.

As for Isidor Rabi, he died at his home in Manhattan from cancer on January 11, 1988. In his last days, he was reminded of his greatest achievement when his doctors examined him using an MRI machine, made possible by his Nobel prize-winning work. The MRI machine happened to have a reflective inner surface, and he remarked: "I saw myself in that machine... I never thought my work would come to this."

In the next chapter we shall look at the other part of Article 53(c) which relates to methods for treatment by therapy - so called "therapeutic methods".

3. Keep your vision clear: Therapeutic methods

Julian Asquith

3. Keep your vision clear: Therapeutic methods

The European Patent Convention (EPC) does not allow patents for methods for treatment of the human or animal body by surgery or therapy.

But when does a method amount to therapy? Some methods, such as taking an appetite reducing drug which causes weight loss, may have both cosmetic and therapeutic uses. In such cases, claims limited to the cosmetic use will generally be allowable. The fact that a chemical product has both a cosmetic and a therapeutic effect when used to treat the human or animal body does not render the cosmetic treatment unpatentable. Of course, cosmetic treatment by surgery would be excluded.

Therapy requires the curing or preventing of a disease or functional disorder of the body, and also requires there to be an effect on the body or part of the body.

Treatments and diagnostic methods are excluded from patentability only if they are carried out on the living human or animal body. Therefore, the diagnostic testing of blood outside of the body is not excluded, whereas a method of blood dialysis with the blood being returned to the same body would be excluded.

Let's take a look at some examples in more detail...

In 1877 Josef Rodenstock founded a company in Germany making ophthalmic lenses and frames. Rodenstock was an innovator who developed and patented numerous improvements to glasses, including sunglasses with UV protection and bifocal lenses with a close-up viewing area.

Rodenstock's company was to become a world-renowned major player in the optics industry, extending over 3 generations of the Rodenstock family. Today, Rodenstock GmbH is a major manufacturer of ophthalmic lenses and spectacle frames with over 5,000 employees, 14 production facilities in 13 countries, and sales in more than 85 countries.

What does Josef Rodenstock have to do with therapeutic methods? Well, wait and see! We shall return to Rodenstock later in this chapter.

In the last chapter we considered the meanings of surgery and diagnosis in the context of Article 53 of the European Patent Convention (EPC), which states that European patents shall not be granted in respect of:

3. Keep your vision clear: Therapeutic methods

(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body...

In this chapter we shall consider the meaning of "therapy" in Article 53.

In the case law of the EPO the first definition of the term "therapy" was given in decision T 144/83. This decision related to an invention for a method of "improving bodily appearance" by taking an appetite reducing drug "until a cosmetically beneficial loss of body weight has occurred."

This invention presented a dilemma to the European Patent Office. The question was whether the invention amounted to a "therapy". On the one hand, a method of weight loss might be used to treat obesity, in which case it could be regarded as a therapy, in the sense that it is treating a disease or disability. On the other hand, a method of weight loss might also be used purely for cosmetic reasons, where there is no disease or disability to treat.

The EPO initially refused the application. The applicant appealed. How would the appeal board solve this conundrum? It is instructive to consider the reasoning of the appeal board, which is set out below.

The appeal board said:

Such exclusions from patentability must be construed narrowly and should not apply to treatments which are not therapeutic in character. As far as the language of the main claim is concerned, it clearly covers a method of cosmetic use and is unrelated to the therapy of human or animal body in the ordinary sense. This is because loss of weight, like gain of weight, is normally not dictated as a desirable effect by medical considerations at all. Cosmetic treatment is "designed to beautify hair, skin, complexion etc. ... or intended to improve appearance (cf. Concise Oxford Dictionary, Tenth Impression, 1980). Therapy, on the other hand, clearly relates to the treatment of a disease in general or to a curative treatment in the narrow sense as well as the alleviation of the symptoms of pain and suffering.

3. Keep your vision clear: Therapeutic methods

a therapeutic treatment and were therefore excluded from patentability under Article 53(c) EPC.

Of course, the exclusion under Article 53 applies only to methods, and not to products. The glasses themselves would therefore have been patentable, but the claims to which the EPO objected were effectively method claims, as they were directed to, "Use of a spectacle lens to correct a spectacle wearer's ametropia" wherein the spectacle lens had certain features.

Ametropia, by the way, is a general term covering any abnormal refractive condition of the eye, including short-sightedness, long-sightedness and astigmatism.

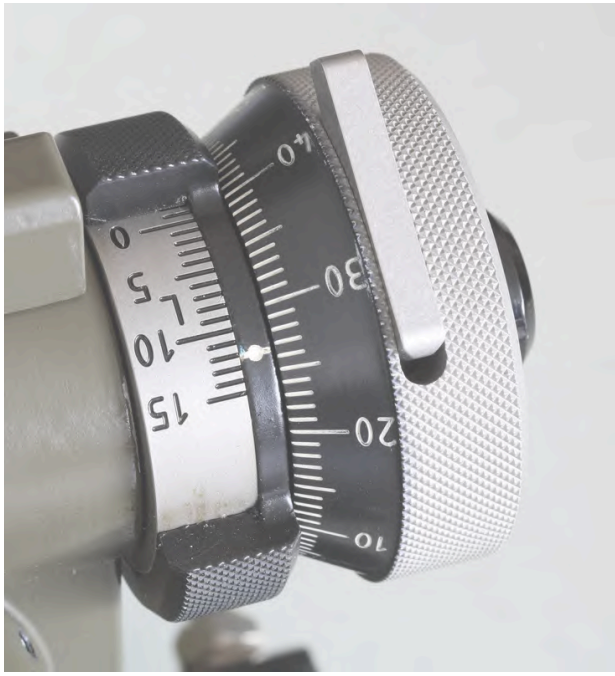
The patent application related to progressive lenses, which were defined in the application as follows:

Progressive spectacle lenses (also called varifocal lenses, multifocal lenses etc.) are usually understood to be spectacle lenses having a different (lower) power in the region through which a spectacles wearer views an object located at a great distance—hereunder referred to as a distance portion—than in the region (near portion) through which the spectacles wearer views a near object. Located between the distance portion and the near portion is the so-called progressive zone in which the power of the spectacle lens continuously increases from that of the distance portion to that of the near portion.

Such "progressive lenses" were already known at the time of the application, and the invention related to a new and clever way in which the power of the lens varied between the distance and near portions.

The appeal board first noted that the claimed use of a spectacle lens for correcting a

spectacle wearer's ametropia was in effect a method, and would therefore be treated as such for the purposes of the decision.



The appeal board noted that, in refusing the application, the Examining Division had relied on decision T 24/91, according to which the term "therapeutic treatment" includes, "any treatment intended to relieve the symptoms of a functional disorder or to cure, alleviate, eliminate or attenuate functional weakness of the human or animal body, or which is capable of preventing or reducing the risk of its acquisition".

Eyesight problems, such as short-sightedness, could be regarded as a "functional disorder" or "functional weakness" of the human body, and therefore a method of treating this could be regarded as therapy.

The appeal board argued as follows (emphasis added):

However, it does not necessarily follow that during the claimed use the body of the person wearing the glasses is treated in any way and that the claimed invention therefore represents a therapeutic treatment of the human body within the meaning of Article 53(c) EPC.

In the board's opinion, therapeutic treatment of the body within the meaning of Article 53(c) EPC presupposes an effect on the body or part of the body to be treated which is the cause of a therapeutic effect. In the present case, the board cannot detect any influence on the body of the spectacle wearer that would lead to or contribute to a therapeutic effect or to the above-mentioned alleviation or attenuation of the symptoms of the spectacle wearer's ametropia. Such relief or attenuation of the symptoms of ametropia is achieved in the claimed invention, as already stated, only by a targeted change in the convergence or divergence of the light beam directed onto the eye of the glasses wearer, without the eyes of the glasses wearer being “treated” in some way.

Therefore, the board here agrees with the complainant's statements, according to

which, in the claimed use, the spectacle lens is used as an external aid and thereby the ametropia of the spectacle wearer is at least partially compensated only by changing the light beam path, as long as the spectacle lens is worn by the spectacle wearer and without affecting the actual ametropia of the wearer's eyes in any way.

Since the claimed use cannot be attributed to any effect on the body, in particular on the eyes, of the wearer of glasses with a subsequent therapeutic effect, the board is of the opinion that there is no therapeutic treatment of the human body within the meaning of Article 53(c) EPC.

The board therefore considered that a "therapeutic treatment" required some intervention on the body or body part to be treated which caused a therapeutic effect.

Recall that Article 53 requires there to be treatment of the human or animal body by surgery or therapy. In the present invention, the glasses did not change the body of the wearer in any way. The eyes of the wearer remained unchanged. If the wearer was short-sighted before wearing the glasses, the wearer remained equally short-sighted after wearing the glasses.

We note that treatments and diagnostic methods are excluded from patentability only if they are carried out on the living human or animal body (G 1/04). Treatment or diagnosis of body tissues or fluids after they have been removed from the human or animal body are patentable, as long as the body tissues or fluids are not returned to the same body. Therefore the diagnostic testing of blood outside of the body is not excluded, whereas a method of blood dialysis with the blood being returned to the same body would be excluded.

Rodenstock have gone on to make many further innovations, including technology that determines and uses the biometrics of the whole eye for optimum lens calculation. Today Rodenstock holds more than 530 patents worldwide and has over 200 pending patent applications for innovations in lenses, frames and instruments. Josef Rodenstock would surely have been proud of these achievements.

4. Push the boundaries: Computers and MedTech

Julian Asquith

4. Push the boundaries: Computers and MedTech

The European Patent Convention states that the following shall not be regarded as inventions:

"schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers"

At first sight it appears that "programs for computers" are not regarded as inventions and therefore cannot be patented in Europe.

However, a computer program which controls an apparatus in an improved way is patentable subject-matter at the EPO. As a result, a MedTech apparatus can be patented even in cases where the only new feature is a new computer program, provided the computer program controls the apparatus in an improved way so as to solve a technical problem.

Many MedTech devices which are controlled by computers or microprocessors thus fall within the realm of patentable devices.

Let's take a look at one of the earliest examples of these principles ...

Back in 1987 the EPO decided a foundational case relating to the patenting of computer implemented MedTech inventions. The case, known as Koch & Sterzel, T 0026/86, related to a computer-controlled X-ray apparatus, and we shall discuss it in this chapter.

In the next chapter we shall look at a more recent case, also relating to computers and X-rays, which was decided some 35 years after the Koch & Sterzel decision.

In 1978 the German company Koch & Sterzel GmbH & Co filed European patent application no. 78101198.6 relating to a microprocessor-controlled X-ray machine. The invention was made by an inventor with the delightful name of Melbourne J. Hellstrom from Severna Park, Maryland, USA. The idea of the invention was to use a computer to control the X-ray generator in such a way as to produce the best possible image resolution while at the same time not overloading the X-ray tubes, so as to prolong the life of the X-ray tubes. It was known that to improve image quality it was desirable to keep the image exposure time as short as possible, to avoid the effects of voluntary or involuntary motion of the patient (e.g. due to respiration) leading to blurring of the image. However, shorter exposure times needed to be balanced against the capacity of the X-ray tube to withstand the larger amounts of heat generated by shorter exposure times.

4. Push the boundaries: Computers and MedTech

The patent was granted by the EPO in 1983, but was then opposed by both Siemens and Philips. The oppositions were unsuccessful, but the opponents then appealed against the decision of the opposition division.

The opponents argued that the invention was excluded from patentability under Article 52(2) (reproduced below) because the X-ray apparatus itself was known, and the only new part of the invention related to a program for a computer.

Article 52(2)
The following in particular shall not be regarded as inventions ..... :

(c)schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

On the face of it, the opponents appeared to have a strong argument. If the only new part of the system related to the computer program, and programs for computers were not to be regarded as inventions, then how could a valid patent be granted?

Koch & Sterzel argued that it was not possible to split the invention into technical and non-technical parts. Instead, the invention needed to be considered as a whole, and viewed as a whole it could be seen that the system produced a technical effect, in the form of the advantages stated above.

So how would the appeal board reconcile these competing views?

The appeal board first noted that the exclusion of Article 52(2) only applies to the extent that the invention relates to a computer program as such. This follows from Article 52(3), which states:

Article 52(3)
Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

4. Push the boundaries: Computers and MedTech

Article 52(3) effectively narrows the scope of the exclusion relating to computer programs.

The board stated that to decide whether the invention is excluded under Article 52(1) EPC it is necessary to determine whether or not it is a computer program as such.

The board considered that the invention was not "a computer program on its own and divorced from any technical application." Instead it was "an X-ray apparatus incorporating a data processing unit operating in accordance with a routine which produces a technical effect in the X-ray apparatus." A technical effect arose because, "optimum exposure is combined with adequate protection against overloading of the X-ray tubes."

The invention was therefore considered to be patentable irrespective of the fact that the X-ray apparatus itself was already known.

It is therefore a general principle that a computer program which controls an apparatus in an improved way is patentable subject-matter at the EPO.

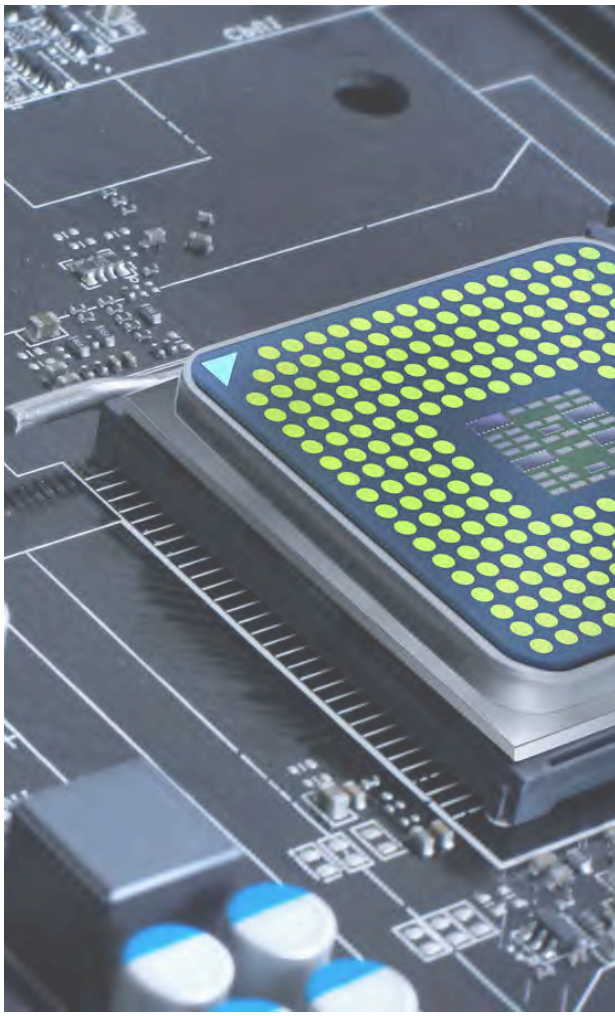
The opponent objected that allowing this application "would render Article 52(2)(c) EPC totally ineffectual because even an ordinary computer program used in a general-purpose computer could then be regarded as an invention under Article 52(1) EPC since each computing operation is carried out with the aid of natural, i.e. electromagnetic, forces."

In response to this the board said, "if the program controls the operation of a conventional general-purpose computer so as technically to alter its functioning, the unit consisting of program and computer combined may be a patentable invention." This is effectively a second way in which computer programs may be patentable - i.e. if the program improves the functioning of the computer itself, for example by increasing the speed of the computer or increasing its virtual memory. For the purpose of MedTech inventions we do not generally need to be

concerned with this second route to patentability, but we note it here for completeness.

Many MedTech inventions are nowadays controlled by computers or microprocessors. These inventions are patentable at the EPO thanks to the principle set out in the Koch & Sterzel decision, which has been widely cited in subsequent EPO decisions.

Although the company Koch & Sterzel GmbH no longer exists, I am eternally grateful for their patent application every time I deal with a patent for a computer controlled device. As for the inventor, Melbourne J. Hellstrom, I have not been able to find out much more about him, except that an obituary online states that he died in 2004 in Severna Park, Maryland, USA, exactly where he made this invention back in 1977.



5. Fortune favours the brave: Computer-assisted methods

Julian Asquith

5. Fortune favours the brave: Computer-assisted methods

Computer-assisted methods may be used during various medical treatments, including surgery. At first sight it might be thought that such methods are excluded from patent protection as being methods of treatment of the human body by surgery or therapy.

However, by careful drafting of patent claims it is possible to avoid these exclusions. This applies both to methods which use computer-assisted devices to collect data from a patient, for example using a sensor, and to methods which use computers to assist doctors in making decisions based on processing of the collected information, for example during surgery.

In particular, when drafting claims in this area it is important to avoid steps which include physical activities which might be regarded as surgical steps.

Let's take a look at an example, and learn from an exceptional entrepreneur at the same time...

In 1982 a 15 year old boy in Bavaria, Germany was given his first home computer, a Commodore 64. The boy's name was Stefan Vilsmeier. Although primitive by today's standards, the 8-bit Commodore 64 was one of the first home computers to be widely used, due to affordable mass-production.

On receiving his computer, Stefan set about teaching himself computer programming, and developed an interest in generating 3D graphics on the computer. When he turned 16 he wrote a book on generating 3D graphics on the Commodore 64, and presented the book to a publisher.

Stefan asked the publishing agency, "For a new book, what is the maximum number of books you have ever sold?" They said the maximum number of books sold was 17,000. Stefan said, "OK, in that case for sales over 15,000 I want double royalties, and for sales over 20,000 I want triple royalties." Not expecting to exceed their record sales of 17,000, the publishing agency agreed to Stefan's proposal.

Stefan's book became a best-seller in its category, selling over 50,000 copies in its first year, bringing him US$ 75,000 in royalties. In today's money that equates to over US$170,000.

In 1989, aged 19, Stefan enrolled at the Technical University of Munich, Germany, to study Computer Programming and Medical Technology. However, the success of his

book had secured him other opportunities to work on computer-related imaging projects, and left little time for studying theory. After just 20 days on campus as a computer science student, Stefan dropped out and founded Brainlab AG in his parents' home to focus on digitizing surgery.

Stefan was still only 19 years old when he founded Brainlab AG using the proceeds of his book sales based on computer graphics on the Commodore 64 computer. Today Brainlab AG has evolved into an international leader in medical technology, employing around 2,000 people in 20 offices around the globe. The company has installed intelligent software and intuitive hardware for use in surgery, radiotherapy and digital operating room integration in over 5,600 hospitals worldwide.

In the previous chapter we considered one of the foundational patent decisions relating to computer-implemented MedTech. That decision related to the computer control of X-ray apparatus. We will now consider a much more recent decision which also relates to the use of computers and X-ray apparatus.

On 13 February 2014 Brainlab AG filed International Patent Application No. PCT/EP2014/052829 for a method of positioning a medical structure. The invention could be used, for example, to allow a surgeon to more accurately position a hip replacement relative to a patient's pelvis. Figure 1 of the patent application is reproduced on the right.

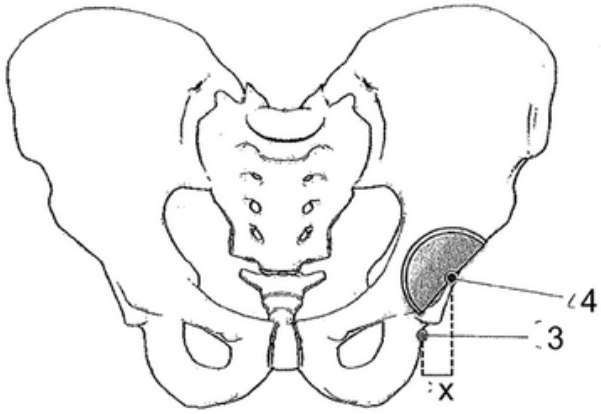
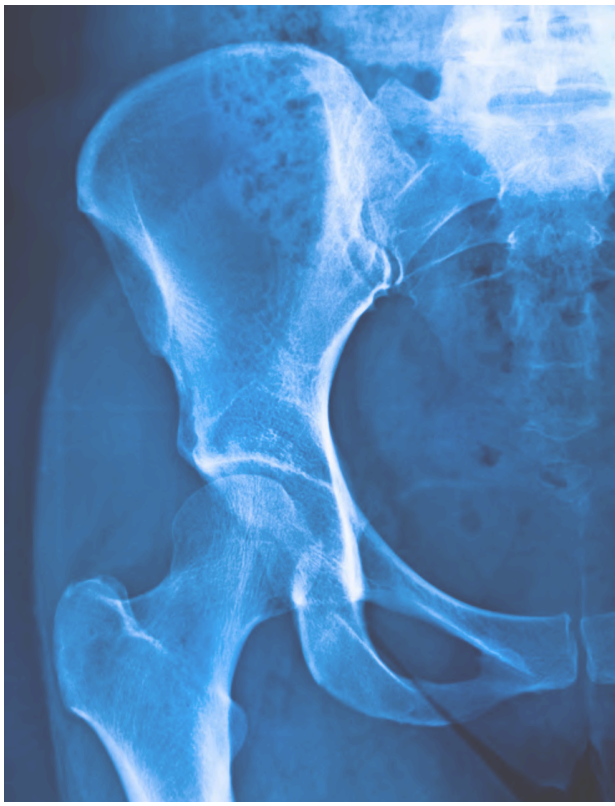


Figure 1

In case you are wondering why this is important, accurate positioning of hip replacements is important because otherwise the patient can be left with a slight difference between the effective length of one leg and the other!

The patient application related to a computer-implemented data processing method for assisting the positioning of a first medical structure relative to a second medical structure, for example the positioning of a medical implant or surgical instrument relative to a bony structure of a patient.

5. Fortune favours the brave: Computer-assisted methods



Given Stefan's background in generating 3D images from the age of 15, it is not surprising that this invention also relates to 3D images. In fact, the invention compares 3D image information (obtained by a surgeon) with 2D image information (obtained for example from an X-ray image), in order to allow the surgeon to more accurately position a hip replacement or other structure. The invention took advantage of the fact that a surgeon may better judge the patient's individual anatomy, and may thus plan a surgical operation more easily, on the basis of two-dimensional projection images such as x-ray images, rather than on the basis of image-free navigation techniques alone, directly on the patient's body.

In one example of the invention, an x-ray image of the pelvis is taken and the positions of two particular points, respectively assigned to the first and second medical structures (called the base point and the reference point in the application) are determined. The distance between these two points in a predetermined direction within the 2D plane of the image is calculated. For example, as shown in Figure 1 above, these points may be easily identifiable points of the pelvis and of a cup implant to be implanted.

The surgeon is then able to palpate the patient's anatomy and the hip implant in 3D using a pointer instrument tracked by a medical tracking system. This allows the actual positions of these two particular points in the three-dimensional anatomical space to be received by a computer.

Finally, the distance between the two points within the three-dimensional anatomical space, when projected onto the X-ray plane, is calculated and compared with the distance previously determined in the two-dimensional X-ray image.

This provides the surgeon with correspondence information describing whether or not these two directional distances correspond. With this information, it is possible for the surgeon to verify the correct positioning of the hip replacement relative to the pelvis.

5. Fortune favours the brave: Computer-assisted methods

Unfortunately the examining division at the EPO refused the patent application, arguing, among other things, that the claims were directed to subject-matter excluded from patentability under Article 53(c) EPC.

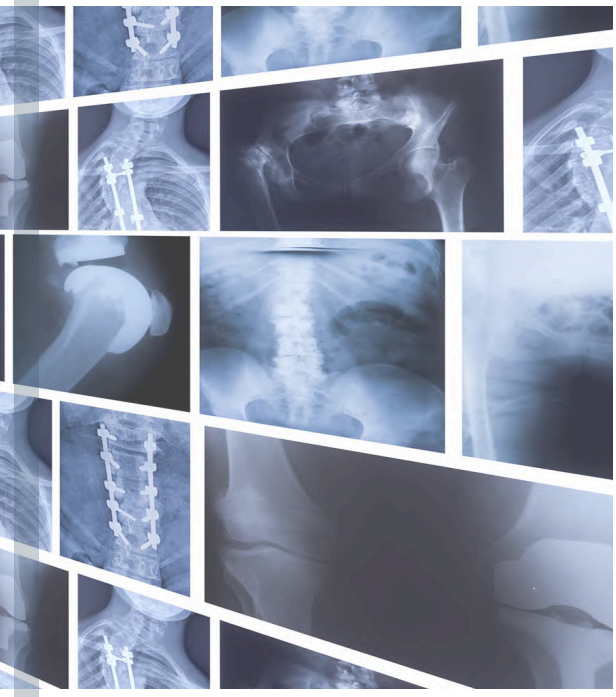
You will recall from Chapter 2 on Surgery and Diagnosis that Article 53 of the European Patent Convention (EPC) states that European patents shall not be granted in respect of:

(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body ...

Claim 1 of the patent application contained a step which effectively included the step of the surgeon using the navigated pointer instrument to palpate the patient's anatomy to allow the computer to "acquire" the 3D positional data mentioned above. The examining division considered this to be a surgical step, and thus to be excluded as a method for treatment of the human body by surgery.

Was it possible to overcome this objection? As we shall see, Brainlab AG were able to make a small amendment to claim 1 which was to prove decisive. They amended the step of "acquiring ... three-dimensional position data" to "receiving, at the processor" the three-dimensional positional data.

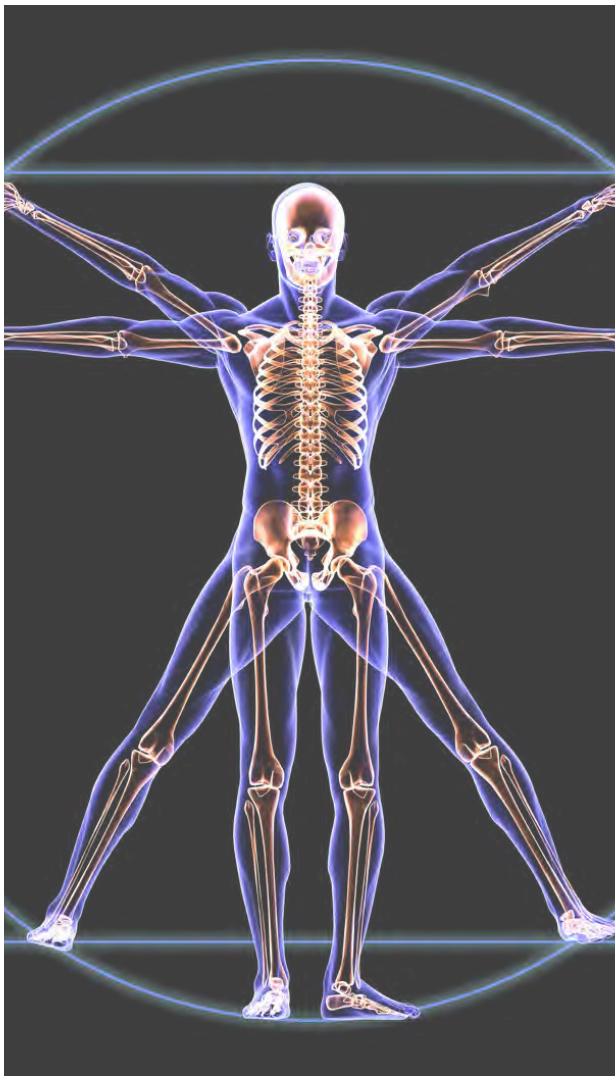
Brainlab AG appealed against the refusal of the patent application, and the decision of the appeal board issued on 9 August 2022 as T 2136/19.



The appeal board stated:

5.1 Claim 1 of the main request is directed to a data processing method "to be executed by a computer". All the method steps recited in claim 1 are explicitly defined as being carried out at or by a digital processor of a computer. These steps are limited to receiving some data at the processor (for example, receiving image data such as data defining an x-ray image) and to determining, by the processor, some data on the basis of other data (for example, calculating directional distances on the basis of position data).

5. Fortune favours the brave: Computer-assisted methods



5.2 In particular, the step of "acquiring, by the computer, three-dimensional position data comprising position information describing the position of the base point (3) and the reference point (4) in three-dimensional anatomical space, in particular relative to the first medical structure (1)", which the examining division had identified as encompassing the surgical step of using a navigated pointer to palpate the patient's anatomy (point 12.3 of the decision under appeal), has been replaced with the step of "receiving, at the processor," this three-dimensional position data.

The Board acknowledges that the three-dimensional position data may well be acquired by palpating the patient's anatomy, thus by a step of a surgical nature; however, by virtue of the amendment above, the step of acquiring the position data itself is not part of the claimed method.

The appeal board noted that the claimed method was for "assisting" a surgeon to position medical structures. However, as explained in the patent description, this assistance was achieved only by providing the surgeon with the correspondence information (i.e. the correspondence between the 2D and 3D measurements) determined in the last step of the method. The appeal board noted that positioning the medical structure was not a step of the claimed data processing method.

The appeal board stated, "More generally, claim 1 does not recite any method step defining or encompassing a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery or therapy. ..... The claimed method is strictly limited to a purely "passive" data processing method which is carried out entirely and exclusively within a computer without causing any effect on the patient's body as a result. It is irrelevant that the claimed method may be performed after or even iteratively during a surgical intervention on the body, as described in the description. In any event, there would be no functional link between the claimed method and any effects of a

surgical or therapeutic nature that would occur during this intervention. Therefore, in the absence of such a functional link, the claimed method as such does not qualify as a method for treatment of the human or animal body within the meaning of Article 53(c) EPC (with regard to the requirement of a "functional link", see G 1/07, point 4.3.2 of the Reasons).

The appeal board therefore concluded that the invention did not fall under the exception to patentability of Article 53(c) EPC.

The appeal board also allowed a separate independent claim for a computer program directed to the method of claim 1, to a program storage medium on which this program was stored, and to a computer running or configured with the program.

This example shows how the exclusion under Article 53(c) EPC relating to methods for treatment by surgery or therapy can be avoided for computer implemented MedTech inventions by careful wording of the claims to avoid physical activities which might be regarded as surgical steps.

Brainlab AG has now filed several thousand patent applications worldwide, of which over 1,000 have already been granted. Clearly patents are of key importance to Brainlab AG in the computer implemented MedTech sector.

Stefan Vilsmeier is still the CEO of Brainlab AG, which he founded in 1989 at the age of 19. Despite his remarkable story of success, starting with the book he wrote at age 16, in a recent interview Stefan said he is actually "the shyest person he knows, and completely introvert".

Stefan explained that he has created a "pretty cool" headquarters in Munich which receives about 1,000 groups of customers every year, and creates a real "experience" for their customers. The building includes a former airport control tower surrounded by a 240,000 square foot facility containing advanced operating rooms where they can demonstrate their technology, and a hall which can seat 440 people. The acoustics in the hall are so good that it is used six times per year for performances by the Munich Philharmonic Orchestra and the Munich Opera Company!

5. Fortune favours the brave: Computer-assisted methods

Stefan said the building also has "Germany's best gym" and a company restaurant, complete with its own pastry chef, to help attract the best employees to work at Brainlab. The top four floors of the former airport tower, now a listed building, are now "Munich's coolest party zone", which is used both for Brainlab's internal parties and rented out 20 times a year for external parties. Stefan said it is so expensive to rent out that they tell people it is also "Munich's most expensive party location"! He said it is maybe the most profitable part of Brainlab!

The story of how Brainlab grew into a world-leading MedTech company from the book of a 16 year old boy is one of the most remarkable MedTech success stories I have come across. Clearly, Stefan has maintained the entrepreneurial skills which allowed him to negotiate such a good deal with the publishing agency at the age of 16, as there is surely no other MedTech company in the world which also enjoys revenue from opera performances and a prestigious party location in an airport tower!

We shall return to the story of BrainLab AG in the final chapter.

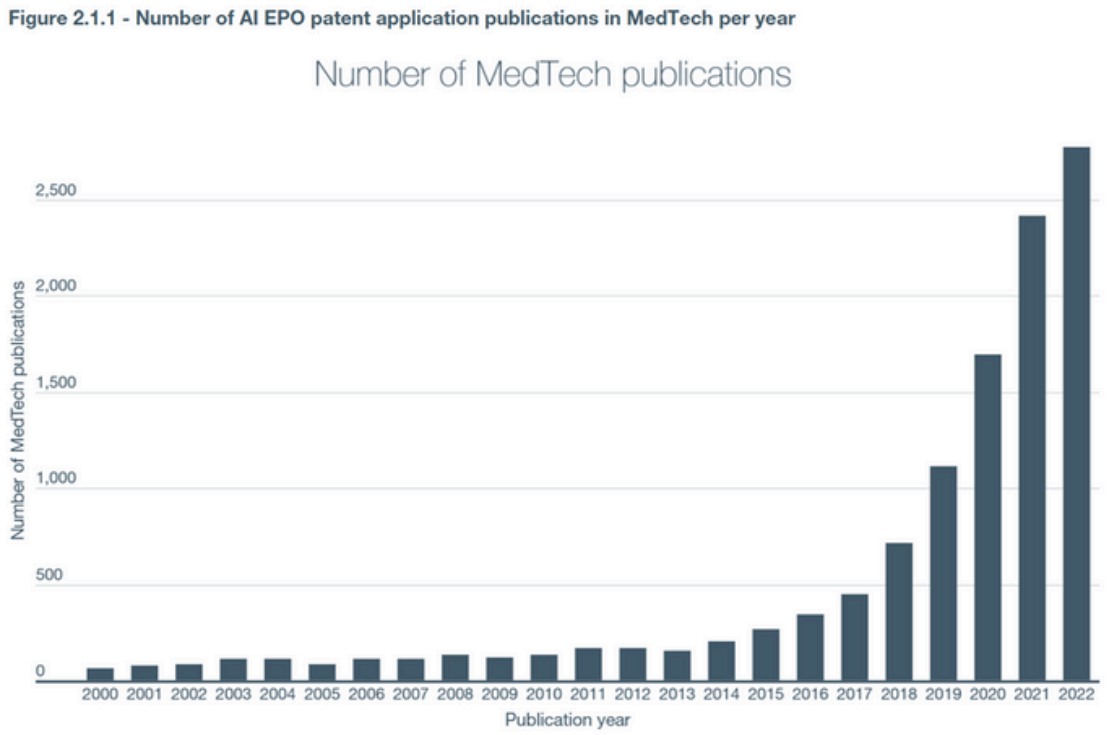
6. Let the heart rule: AI and MedTech

Julian Asquith

6. Let the heart rule: AI and MedTech

For the last four years Marks & Clerk has produced an annual AI Report, providing data and insights from our many experts in AI. The following graph, showing the number of AI patent applications in MedTech published by the EPO each year, is taken from our 2023 AI Report.

Figure 2.1.1 - Number of AI EPO patent application publications in MedTech per year



As can be seen from the graph, the number of publications of European patent applications for AI inventions in the MedTech sector has increased virtually exponentially over the last decade.

Let's look at a decision of the EPO relating to a MedTech AI invention, which has helped to drive the trend shown above...

Teuvo Kohonen was born in Finland in 1934. Growing up in Finland he spent time in the Scouts, where he would have learnt map reading, and maps were to form an important part of his career. He was fortunate to have a good teacher in physics, which led to him doing a PhD on the lifetimes of positrons, and starting life as a physicist.

Teuvo became a professor in physics in Finland but, as there were not enough university academics at the time, he also had to teach students about computers. He had never been taught this subject, and so a few weeks before each lecture he hastily read up about computers. In 1962 he came across an article on computer learning which interested him greatly, and so began his interest in artificial intelligence.

6. Let the heart rule: AI and MedTech

Teuvo Kohonen was to become one of the world's best-known neural network researchers. He made pivotal contributions in the field of artificial neural networks, and is best known for developing the Kohonen map, which brought Finnish artificial intelligence research onto the world stage in the early 1980s.

A Kohonen map, also known as a Self-Organizing Map (SOM), is a machine learning technique which uses a (usually) two-dimensional representation of a higher dimensional data set while preserving the topological structure of the data. Kohonen maps have been used in finance, trade, natural sciences, linguistics, speech recognition and robotics. The Kohonen map was considered by experts to be one of the most significant inventions in computational science, and has been the subject of more than 8,000 scientific papers..

On 3 September 1996 a UK company, Cardionics Limited, filed International Patent Application No. PCT/GB96/02169 for a heartbeat monitoring apparatus and method using a Kohonen neural network.

The invention related to the analysis of electrocardiograph signals obtained from a patient using a neural network to monitor changes in the functioning or performance of the heart of a patient.

Prior to the invention it was known to detect electrical signals of the heart by means of conductive pads attached to the patient's chest and directly wired to a suitable machine which provided a graphical trace of the waveform for analysis by a doctor.

The invention sought to provide a heart monitoring apparatus which could monitor changes in heart condition automatically.

Figure 1 of the patent application, shown on the right, illustrates a typical electrocardiograph trace wherein various features P, Q, R, S and T can be seen. The shape and size of each of the features is an important indication of the condition and operation of the heart.

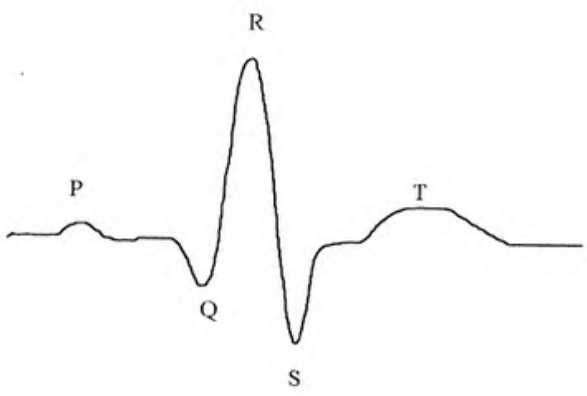


Fig 1

Instead of using a fixed apparatus to display such traces, the invention envisaged that the patient would wear a portable heart monitor device, and that this would be connected wirelessly to a remote base station, thus allowing the patient's heart to be monitored whenever the patient wore the portable monitor device.

Analysis of the electrocardiograph signal could take place either in the portable monitor device itself, or in the base station or another computer.

Feature mapping in a Kohonen feature map is a process in which example training vectors are clustered in feature space.

In the invention, pre-processed values from an electrocardiograph signal were used to define a vector position in a multi-dimensional feature space. The dimensionality of the feature space is determined by the number of features measured. In some embodiments of the invention 64 values were provided, and the feature space was therefore a 64 dimensional space. In simple terms, in a Kohonen map these vectors can be represented in a 2D pattern space.

Figure 10 from the patent application is shown on the right, and illustrates a simple case of a two dimensional pattern space having eight reference vectors (shown as small circles), each with their own area of influence.

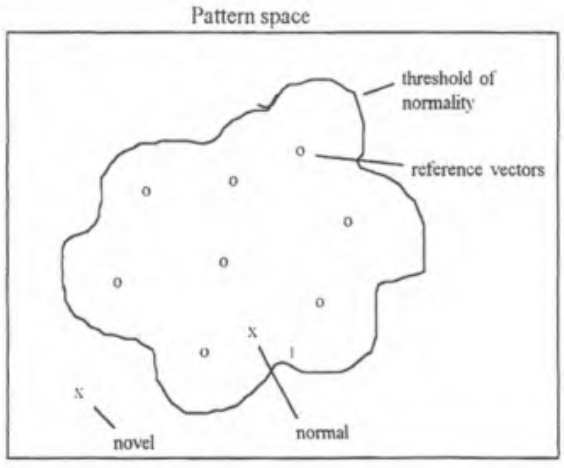


Figure 10 also illustrates two electrocardiograph values (shown using the letter "x") for this two dimensional hypothetical example: one representing a normal electrocardiograph signal which falls within the threshold of normality and one representing a "novel" (i.e. unknown) electrocardiograph signal which falls outside the threshold of normality.

According to the invention, this approach could be used to define different regions in the 2D pattern space representing different specific heart conditions. During the monitoring phase, when the patient is wearing the portable heart monitor, if the electrocardiograph signal values fall outside the threshold of normality and inside a region of abnormality, the apparatus can detect and indicate the specific heart condition which has arisen.

6. Let the heart rule: AI and MedTech

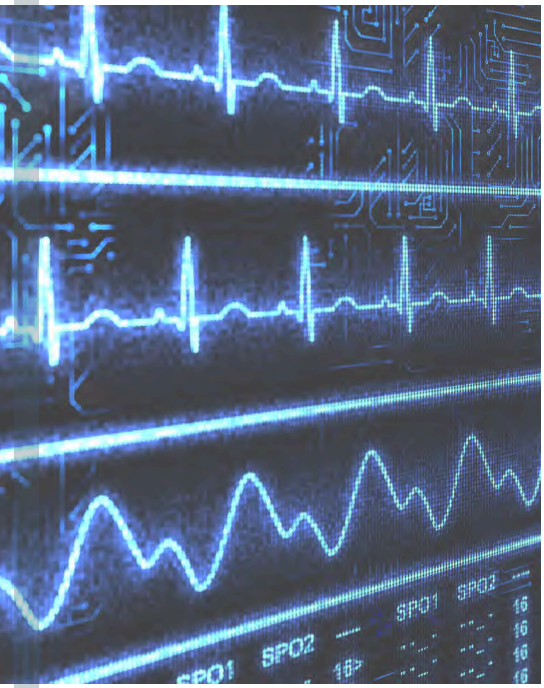
For example, a region of the 2D pattern space may represent a myocardial infarction, commonly known as a heart attack, caused by reduced blood flow to the muscular tissue (myocardium) of the heart. Myocardial infarctions can sometimes be mild, and can therefore sometimes go undetected in the absence of heartbeat monitoring.

The European patent application granted on 15 December 1999 as European Patent No. EP 0 850 016 B1.However, European patents can be opposed by third parties within 9 months of grant, and the patent was opposed on the last day of the 9 month period. Unfortunately for the patentee, the opposition division revoked the patent on the ground that the invention was obvious. The patentee appealed.

After two rounds of oral proceedings the appeal board finally gave its decision (T 0598/07) on 19 May 2010, some 10 years after the original opposition, and nearly 14 years after the application's filing date. Fortunately, these days appeals are much quicker at the EPO, which has an objective to settle 90% of cases within 30 months.

The appeal board noted that the independent claims had now been limited to a Kohonen neural network, and more specifically recited that:

..... the n-dimensional vectors representative of the monitored ECG are compared with a first n dimensional volume representative of irregular heartbeats, which are spurious with regard to monitoring heart conditions, and subsequently with a second n dimensional volume representative of regular heartbeats.



The appeal board had to consider what prior art documents indicated to be already known at the priority date of the application. There were two documents which were particularly relevant.

Document 1 disclosed a heart monitoring apparatus with input means for receiving an electrocardiograph signal from a patient during a monitoring phase. Pre-processing means could carry out feature extraction in order to extract important features of the shape of a sequence of pulses of the electrocardiograph signal to obtain a plurality n of values representative of the shape of said sequence of pulses of the electrocardiograph signal.

However, the invention differed from Document 1 in that the plurality n of values obtained in the invention was representative of the shape of each pulse of the electrocardiogram, and not of a sequence of pulses as was the case in Document 1. A further difference was that the invention used Kohonen networks.

Document 2 also disclosed a heart monitoring apparatus, which could carry out feature extraction to extract important features of the shape of each pulse of the electrocardiograph signal, and which could store a plurality of four-dimensional reference vectors, each said four-dimensional reference vector comprising four values representative of the shape of a reference pulse.

At this point you might be thinking that all was lost, as Document 2 is quite close to the invention. However, the board noted the following two important features of the invention which were not present in Document 2:

a) The n dimensional vector representative of each pulse was first compared with an irregular heartbeat n dimensional volume, to identify distinctive irregular beats, and subsequently with a regular heartbeat n dimensional volume; and

b) The data processing was carried out by a Kohonen neural network.

The board noted that the technical effect (advantage) obtained by feature (a) was to allow the second comparison with the regular heartbeat n dimensional volume to be carried out only for n dimensional vectors formed from a regular heartbeat which did not include a distinctive irregular heartbeat.

This allowed the invention to improve the signal to noise ratio and thereby reduce the number of false identifications of novel electrocardiograph signals,

The board next had to decide whether the invention was excluded from patentability by our old friend Article 53(c), which you will recall states that states that European patents shall not be granted in respect of:

(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body ...

One of the independent method claims included the step of "outputting an indication" (e.g. an alarm) if the heartbeat was abnormal. Although certain examples in the patent specification allowed the system to provide an audible or visual indication of specific heart conditions, such as the myocardial infarction mentioned above, this feature was not included in the claims.

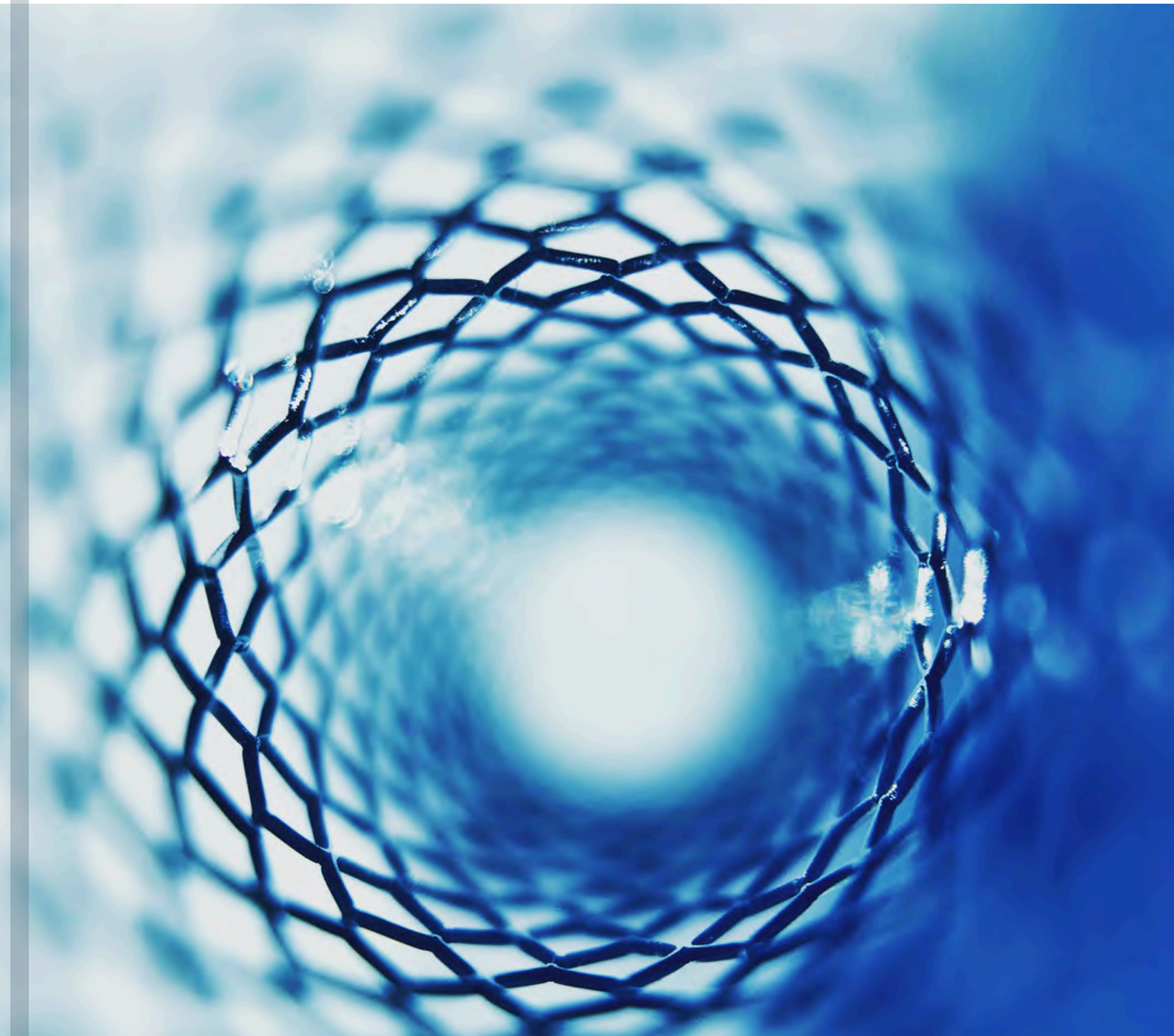
Therefore, the claims did not include a step relating to diagnosis for curative purposes stricto sensu representing the deductive medical decision phase. The diagnosis would instead be carried out by a physician after the alarm had been sounded.

For these reasons the patent was allowed.

From this example it can be seen that a heartbeat monitoring method using a neural network to identify irregular heartbeats was considered patentable by the EPO, and was found to make a technical contribution.

7. Don't be afraid to burn the midnight oil: Additive Manufacturing and MedTech

Julian Asquith



7. Don't be afraid to burn the midnight oil: Additive Manufacturing and MedTech

3D printing is now widely used in a variety of MedTech areas, for example in the manufacture of custom-fit artificial limbs (prostheses), external supporting devices (orthoses) and implants for operations and dental procedures. Additive manufacturing (a more general term, which includes 3D printing) also allows the production of customised drugs by printing a patient-specific mix of drugs into a single pill.

There are a number of special considerations to take into account when patenting inventions relating to additive manufacturing / 3D printing.

First, it is important to realise that almost all products can, at least in principle, now be produced by 3D printing technologies, and this allows interconnecting parts to be produced with structures which were not previously practical or possible. Such structures must be foreseen when drafting patent claims to ensure that they fall within the scope of the claims.

Secondly, 3D printing uses computer files which may be copied and transmitted quite separately from the products themselves. For this reason, when patenting inventions relating to 3D printing it is important to include claims which protect these files, and/or which will be infringed if such files are used.

Computer simulations are often used when designing medical items to be 3D printed. In 2021 there was a significant change in the law when the Enlarged Board of Appeal of the European Patent Office decision G1/19 relating to computer simulations. Under the new law, claims to simulations must in effect specify what practical use is made of the simulation, and such practical uses must also be given in the description of the patent specification.

Let's take a look at an example of a patent for a personalised heart stent, which was made possible by the work of a remarkable young engineer in 1983...

In 1983 Chuck Hull, a young American engineer, called his wife from a small laboratory late one night. There was something he wanted her to see. Could it not wait until the morning? She was in her pyjamas, after all. No, it could not wait. He asked her to get dressed, and come to the laboratory straightaway.

What was so important that it could not wait until tomorrow?

7. Don't be afraid to burn the midnight oil: Additive Manufacturing and MedTech

Chuck had been working at a company called Ultraviolet Products, which worked with UV-curable materials used for coatings for furniture, such as tabletops. After the material was applied, UV light was used to harden the coating. Chuck realised that it might be possible to cure multiple layers of such a material in order to produce a plastic object. In a small laboratory, he started playing around at evenings and weekends to see what he could produce.

He used photopolymers, which are typically acrylic-based materials that are liquid until they are exposed to ultraviolet light, at which point they turn solid. He created a process in which you start with a container filled with liquid photopolymer, and use a computer to draw on the surface of the liquid using a focussed UV light. When the UV beam strikes the surface, the photopolymer changes to a solid, thus producing the first layer of the object. The object is then lowered by a small amount before producing the next layer, and so on, until a whole object has been produced, at which point the object is lifted and emerges out of the liquid.

When he called his wife late one night in 1983 Chuck Hull had at last succeeded in "printing" a 3D object. He wanted his wife to be the first to see it.

Chuck successfully protected his method by means of US Patent 4,575,330, granted in 1986, in which he coined the term “stereolithography” for this process.

Stereolithography, or "SLA" printing, soon became a widely used technique in rapid prototyping and direct manufacturing. Chuck co-founded 3D Systems, and in 1987 his company produced the first ever 3D printer.

Today, Chuck has 93 US and 20 European patents to his name, and in 2014 he was awarded the European Inventor Award in the Non-European countries category by the European Patent Office.

7. Don't be afraid to burn the midnight oil: Additive Manufacturing and MedTech

As we shall see, Chuck's method can be used with great efficacy in the MedTech industry.

On 17 February 2015, Siemens Healthcare GmbH filed European Patent Application No. 15714009.6 relating to a personalised heart vessel stent which could be produced by 3D printing methods, including stereolithography.

In Chapter 5, about AI and MedTech, we looked at a patented AI system which is capable of detecting reduced blood flow to the heart (so-called myocardial infarction). Now we will consider an invention which aims to treat such a condition using 3D printing.

The Siemens application explains:

Cardiovascular diseases (CVDs) have become the prime cause of death around the world. More people die of CVDs than any other cause. ... One of the common ailments in CVDs is the deposition of plaque in cardiovascular arteries. The plaque deposition can block the blood flow in the heart thereby resulting in myocardial ischemia [a lack of blood flow to the heart muscle] or myocardial infarction [commonly known as a "heart attack", caused by cessation of blood flow to the muscular tissue of the heart, known as the myocardium].

One of the most common remedies for CVDs is deploying stents into the arteries where a significant plaque deposit is found. Currently, there are a number of prefabricated stents available in different sizes and shapes which can be inserted in the arteries based on an assessment by a doctor. However, the prefabricated stents cannot be personalized according to the nature of the plaque deposit in the affected vessel of the subject. Recently with the advancement of the additive manufacturing there is scope for manufacturing personalized stents.

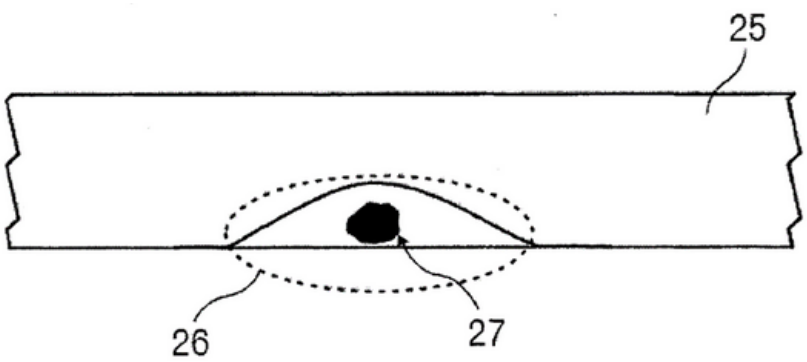
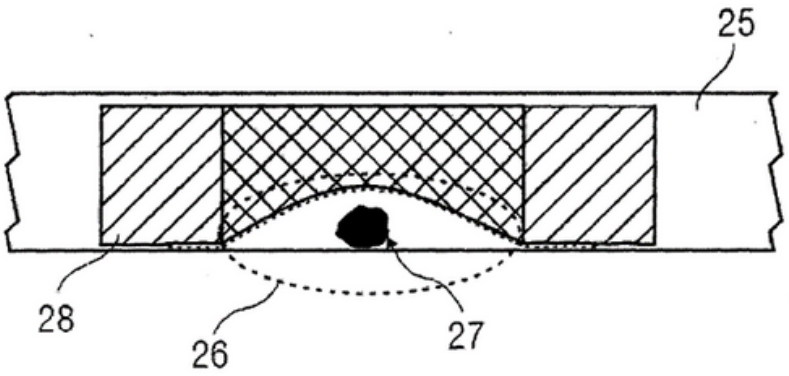


Figure 3 of the Siemens patent is shown on the left. The figure shows a blood vessel 25 containing a region of interest (ROI) 26 containing a calcified plaque region 27, causing a "stenosis", which is a narrowing of the blood vessel 25.

7. Don't be afraid to burn the midnight oil: Additive Manufacturing and MedTech

According to the patent application, images of the blood vessel could be produced by suitable scanning technology, such as ultrasound, MRI or computerized tomography, and a model generation module could then generate a personalized multidimensional model of a suitable vessel stent for the patient. In particular, the design and composition of the personalised vessel stent could be such that the stent exerts minimal pressure on the calcified region 27.

An example of such a personalised stent 28 is shown in Figure 4 of the patent, shown below.



As can be seen from the figure above, the stent 28 is designed to hold the blood vessel 25 open, while at the same time curving around the calcified region 27, so as to reduce pressure on this region.

Siemens were successful in obtaining a granted patent for a method and device for customising the vessel stent, with the method taking into account, "a length, a thickness, a composition, a level of calcification and a distribution of a plaque deposition at the stenosed region; the personalized vessel stent (28) being composed of a plurality of materials so as to exert minimal pressure on the calcified region (27)."

The Siemens application discussed above also described a module configured to simulate inflation of the personalized vessel stent within the coronary vessel of the patient. The simulation could be used for verifying the inflation of the personalized vessel stent under different pressure values of an inflating balloon, and to verify the fit of the stent with respect to the stenosed (i.e. narrowed) region of the vessel. In case the stent design did not appear to fit well in the simulation, the design of the stent could be remodelled for a better fit.

Computer simulations of this sort are used in a variety of MedTech technologies, so it is worth taking a moment to consider the patent position in relation to such simulations.

7. Don't be afraid to burn the midnight oil: Additive Manufacturing and MedTech

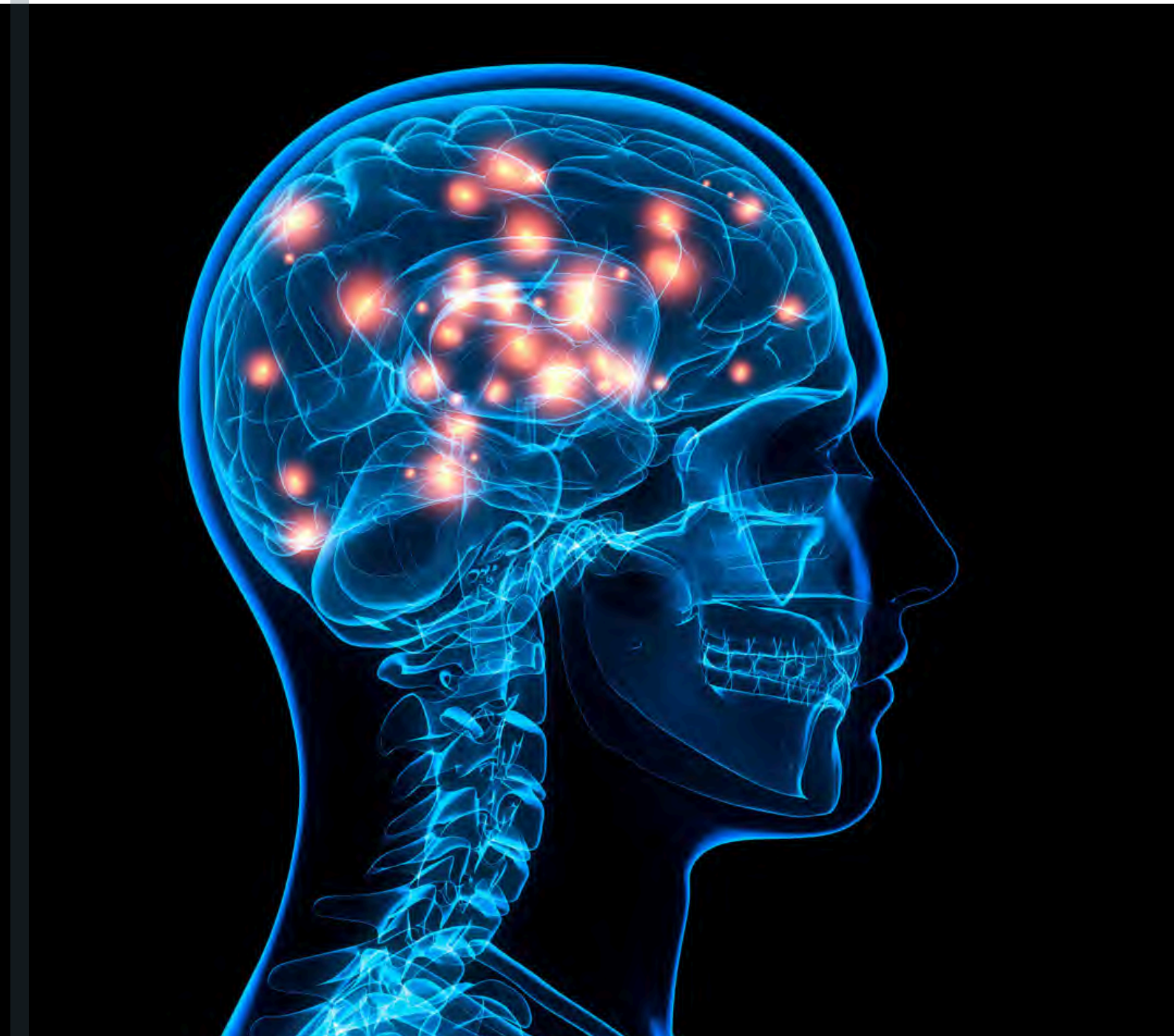
In 2021 in Europe there was a significant change in the law when the Enlarged Board of Appeal of the European Patent Office (EPO) issued its decision G1/19 relating to computer simulations. Before this decision a leading earlier case (T1227/05, which related to the simulation of a circuit subject to 1/f noise) held that simulation of a technical system was sufficient to establish a technical purpose. Under the new law claims to simulations must in effect specify what practical use is made of the simulation, and such practical uses must also be given in the description of the patent specification.

Of course, in MedTech inventions of the type we have been discussing there is an obvious practical application in the form of improving the fit of the personalised item to the patient. Therefore, provided such simulations are limited to these or other practical applications, the simulations should be patentable at the EPO, provided other requirements such as novelty and inventive step are met. In addition, the resulting products (in this case the personalised heart vessel stents) would also be patentable in themselves, again provided that the requirements of novelty and inventive step are met.

We should be thankful for pioneers like Chuck Hull.

8. Strategies for success: The remarkable story of BrainLab AG

Julian Asquith



8. Strategies for success: The remarkable story of BrainLab AG

In this chapter we will follow the remarkable success story of BrainLab AG, which we touched on in Chapter 5. The founder of the business, Stefan Vilsmeier, has much to teach us about how he created this world leading medical technology company employing 2,000 people in 20 offices around the globe.

In particular, success does not always involve following the crowd. Don't be afraid to be different. Don't accept limits for your company - the possibilities are limitless.

Bring people together from different areas of your company to achieve cross-departmental communication and creativity. The solution to every problem always co-exists with the problem.

Push yourself outside of your comfort zone, and don't be afraid of imperfection. Learn from others, including the people you hire, and above all have fun.

Let's dive in to the story, and see how Stefan created this astonishing company from nothing...

If we want to learn about strategies for success in a MedTech business, where better place to start than the story of a successful MedTech business, and who better to tell us about strategies for success than the founder and leader of that business?

We now return to the remarkable story of BrainLab AG, which we touched on in Chapter 5. As you may recall, BrainLab AG is a world leader in digital medical technology, but it was started in 1989 by Stefan Vilsmeier when he was only 19 years old using the proceeds of a book which he wrote at the age of 16.

How did Stefan grow this company from nothing to a company employing 2,000 people in 20 offices around the globe? What can Stefan teach us about the mindset of success and growth? Stefan's story is such a fascinating one that it is worth telling the story in some detail. Much of the advice below is taken from a recent interview with Stefan.

Stefan notes that he is super-shy. He never imagined he would start a company, but he says he is very persistent and he just wanted to see his ideas and concepts succeed.

In 1987 Stefan finished high school. On the strength of his book about 3D computer graphics on the Commodore 64 home computer, he was invited by the University of Vienna to help them in their Neurosurgery Dept. They were struggling with some

8. Strategies for success: The remarkable story of BrainLab AG

He had no idea what to expect, but on his first trip to the University of Vienna he was shown some images from Computer Tomography and Magnetic Resonance Tomography. He was struck, and completely intrigued, by the aesthetics and the beauty of the images. As we shall see, aesthetics and beauty were to play a central role in his vision, and we shall return to these later in this chapter.

When Stefan went to Vienna he noticed that surgeons were performing brain operations based on their memory of the images mentioned above. He realised that software could provide a better solution, and he started work on software for more accurately determining precise locations in the brain.

Stefan had to stop this important work to do mandatory national service in Germany. He became quickly bored with national service, and his mind was still on the problems of brain surgery at the University of Vienna. So what did he do?

Stefan decided to do something he says nobody had done before. He wrote a letter to the Minister of Defence in Germany. Stefan notes that his letter caused a certain amount of bewilderment in the German military, but eventually the letter made its way to the Minister of Defence.

Two weeks later, Stefan was given an immediate release from his military service, to the amazement of those around him. It was simple, said Stefan. His letter had explained the work he wanted to do relating to brain surgery, and how it would have much more impact on society than "sitting there cleaning a rifle".

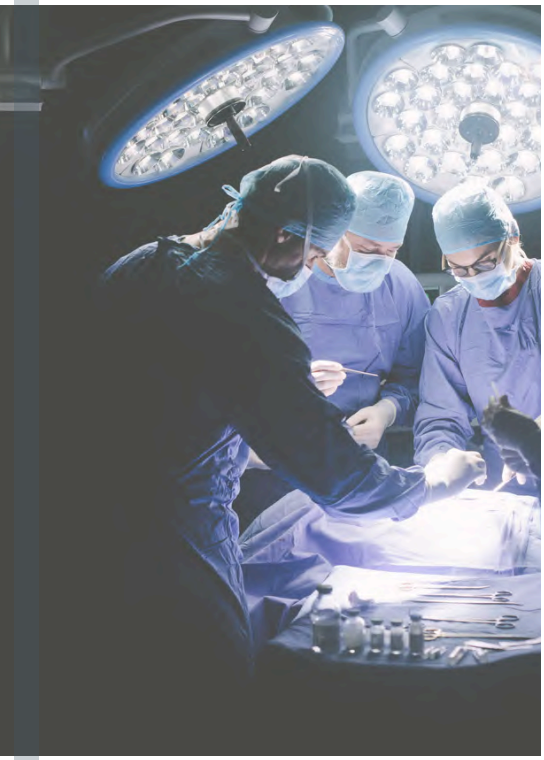
Stefan explains that his parents always gave him a sense of being special, and that always encouraged him to fight for what he wanted. He explains that he was later to take exactly the same mindset into the sales of his products. He says that even if he had no idea how to sell something, he always went to the customer with the mindset, "You're going to buy my product. You just don't know yet - but you will." He had no doubt in his mind that that is what would happen, and as we shall see he was to have

some remarkable success.

Having cut short his army service, Stefan returned to his work for the University of Vienna. He was working with stereotactic brain surgery, which uses a stereotactic device mounted on the patient's head. Stefan describes the device as like a sextant, used for accurately locating positions in the brain. He says that previously surgeons took X-rays, and made manual calculations with rulers about positions in the brain. Stefan created software which not only accurately located positions in the brain, but also showed and visualised what brain tissue would be damaged along the way to a particular point in the brain. BrainLab still does stereotactic targeting, but today it is less than 1% of their revenue.

After 6 months he thought he should seek a formal education, and he started studying Computer Science at the Technical University of Munich. Stefan says that, having become passionate about writing software for brain surgery, a formal computer course was not for him. He dropped out of his university course after just 20 days.

Stefan says that he had now, in effect, created an artificial crisis, and he had no choice but to drive BrainLab forward. He continued to write software for brain surgery while living in his parents' basement, and the money from his book success carried him through the early years.



In 1992, after 5 years, he had all but run out of money. Things were getting desperate. What would this young entrepreneur do next?

Stefan knew that the Congress of Neurological Surgeons held an annual scientific meeting in Washington DC. Could he sell his software at such a congress? If so, he would need a sales booth at the congress, and sales staff, but he didn't have either, and very little money. What to do next?

Stefan looked around his parents' garage. How hard could it be to build an exhibition sales booth? Could he build one here, in his parents' garage? It had to be worth a try.

8. Strategies for success: The remarkable story of BrainLab AG

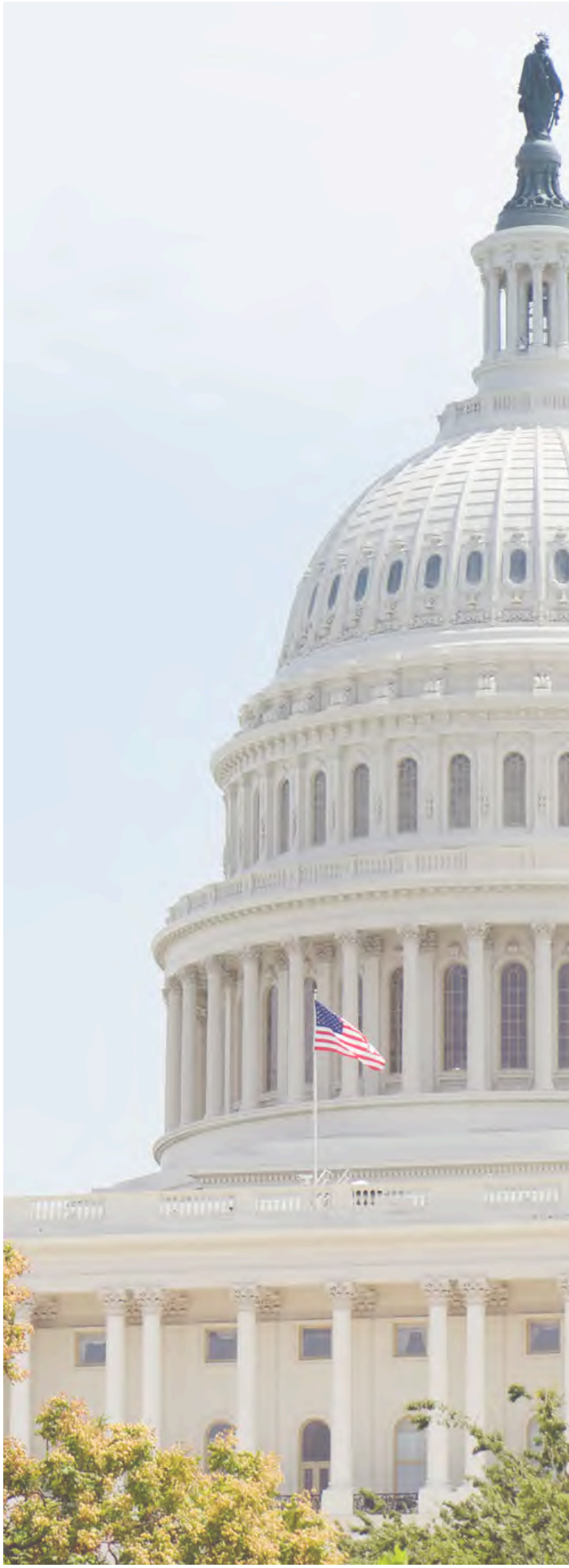
Stefan built a booth in his parents' garage, and loaded it into suitcases, far exceeding the airline's luggage weight allowance. He was to tell the airline that he was a student, and needed this extra weight to transport his thesis to the US, thus avoiding the airline surcharges. Well, maybe this was true in a way, but it was also hugely ironic coming from a man who had dropped out of university after 20 days!

He still had no sales staff, so he took his sister with him. They couldn't afford the hotels in Washington DC, so they stayed out of town. Nor could they afford the union labour rates for staff to set up their booth, so they waited until after hours, and set it up themselves.

The next morning, at the 1992 Congress of Neurological Surgeons in Washington DC they arrived at a booth which looked much like most of their competitors. They got their first sales from customers around the world, including North America, Germany, Taiwan and South Africa. Stefan jokes that BrainLab immediately became a company with global sales!

In 2019 Stefan had an experience which transformed his vision for the company.

Stefan has a love of both technology and art. He says it is important to address the right and left sides of the brain equally. The left side of the brain is more associated with logic, whereas the right side of the brain is more associated with art and creativity.



8. Strategies for success: The remarkable story of BrainLab AG

In Chapter 5 we mentioned that the BrainLab buildings in Munich contain a hall seating 440 people which is used for performances by the Munich Philharmonic Orchestra and the Munich Opera Company. What we didn't mention is that Stefan is also a keen collector of art, and the hall houses part of his art collection.

In 2019 Stefan was profoundly impressed and moved by the art of Anselm Kiefer, who he describes as the most interesting German artist alive.

Anselm Kiefer moved to France in 1992, where he created a 35-hectare studio compound from a derelict silk factory. He created buildings and a maze of huge underground caves and tunnels, which all formed part of his art, alongside his paintings. Anselm Kiefer's studio complex in France was the subject of a documentary film, Over Your Cities Grass Will Grow (2010), which opened at Cannes in 2010.

When Stefan visited the 35-hectare studio complex of Anselm Kiefer in 2019 he was staggered by the scale of what this artist had created. But that was not all. Anselm was in the process of creating another building which was large enough to allow Anselm to paint a 50ft high painting.

Stefan was struck by the artist's incredible vision. He said, this artist is "limitless" - he just doesn't accept any boundaries or limitations whatever. The experience of visiting Anselm Kiefer's art compound was to move Stefan so intensely that he describes feeling the adrenalin from the visit for a full two weeks after the visit.

After the visit, Stefan describes feeling ashamed of his own limited vision. He had just seen an artist who did not accept limitations or boundaries. Why should BrainLab be different? He realised the limitations of what BrainLab could achieve were just in his head.

Stefan says, sometimes we just need an external trigger to grow our vision bigger.

8. Strategies for success: The remarkable story of BrainLab AG

When he returned to BrainLab from his visit to Anselm Kiefer's artistic compound, his colleagues didn't know what had hit them. Some of them thought his ideas were crazy, but he was much less willing to accept restrictions. As we saw in Chapter 5, Brainlab AG now occupies a former airport control tower surrounded by a 240,000 square foot facility containing advanced operating rooms, a concern hall, Germany's best gym, a restaurant with a dedicated pastry chef, and Munich's most expensive party location. The "limitless" imagination of the German artist, Anselm Kiefer, are indeed in evidence at BrainLab AG!

Stefan hires people of all ages, but he likes hiring young people because they haven't learned what the limitations are. If you have somebody experienced, Stefan says, they can give you all the reasons why something can't be done. Younger people have a different perception, and things that seem impossible can be accomplished by people who "just don't know any better".

Stefan explains that, for every problem, the solution to the problem always co-exists with the problem. You need an expansion of your horizon, to discover the solution which was always there.

Stefan believes it is crucial to expose everybody in the company to "the problem". People in, for example, accounting should go to the operating room once a year, and see how the company's technology is impacting their customers and their patients, so they can understand how their work is part of that.

To solve problems you need to get people connected. You need a lot of space for informal communication. That's the idea behind why BrainLab has the best gym and the best restaurant - because those are areas where people meet.

Stefan says employees do small group training in the gym. They work out with a personal trainer and colleagues from different departments. That breeds cross-departmental communication and creativity, and that's where the best ideas are born.

Stefan says, always talking to the same people is like committing mental incest - you are just feeding what you already know, and what you want to listen to.

He says everybody should make an effort to push themselves out of their own comfort

zone. He has to do that all the time, as he is naturally very shy. Push yourself out of your own comfort zone, and you never know what the day will bring.

On the question of perfection, Stefan says you need to accept that you will not be perfect. What you need is the "courage for imperfection" - the courage to try things anyway, even if you are not perfect. Interestingly, he has sometimes not hired people because they have been too perfect in the interview! He is always looking for something that is a bit "off", which makes the person more personable and authentic. Being authentic is the most important thing, he says. We need authentic people to build meaningful relationships between employees and with clients. It's the same with jazz and many different types of music. It is the imperfection which is really the "spice of life".

Stefan has been in charge of the company for 34 years, which he says is very unusual. He has never worked at any other company. Everything he has learned, he has learned from people he has hired. Hiring people who could do certain things better than him made it easy for him to let go of those things.

There's hardly anything in BrainLab he hasn't done at some point, but he feels privileged to have worked with the people he has hired, and they have been his mentors and coaches. He looks for people who are outspoken and open - people who are willing to disagree with him and have debates.

He takes management associates, who have done an MBA, for example. They are there to work on corporate projects - but what they don't realise is that they are teaching him about new ideas at the same time. He says that is a great coaching and mentorship program for him, although he doesn't like to openly admit it all the time!

As well as art, Stefan has also been influenced by films. In the early 2000's Stefan saw the movie Minority Report, in which Tom Cruise uses a special screen. He thought, that's what we need for surgery!

He gave the idea to one of his best project managers. He gave him 18 months and a budget of $1m. In 2006, they launched the product, which is a large touch screen for surgeons. Touch screens are more common today, but the product was released about 6 months before the iPhone was first introduced. The BrainLab device and software is now in thousands of operating rooms.

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Stefan still does a lot of customer demos himself. He says you shouldn't buy software from a company where the CEO can't give a decent demo of the software.

More recently BrainLab has created Buzz Virtual, which is a small box which can be used with any screen. They have software running on a server which they can bring to the screen, which can for example bring AI labelling of anatomy.

BrainLab's technology is now in 6,300 hospitals in 120 countries. BrainLab considers there are about 7,000 hospitals doing serious surgery, and BrainLab is therefore in 90% of these.

In 2020 Brainlab announced the acquisition of Level Ex, a Chicago-based company that creates medical video games designed to advance the clinical skills of physicians and surgeons.

With a user base of more than 600,000 medical professionals, including half of all medical students in the US, Level Ex creates mobile, AR and VR games which allow surgeons to practice and develop their skills. The games are super-realistic, using the latest computer graphics from the gaming industry.

Stefan says that as an entrepreneur you must expect lonely moments. You may have received a lot of advice from people, but ultimately you have to make the decision.

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There is never a right or wrong decision. You need to make sure that the decision that you took ends up being the right decision.

Stefan says sometimes we get mentally stuck with plan A. Sometimes you have to give plan B a little more love. He would encourage everyone to spend a bit more time thinking about plan B.

Stefan gives an example. They once ran an advert in a journal for a new product, even though the product was not yet ready and they didn't have a photo of the product. As they didn't have a photo, the advert showed somebody walking through the desert, with the caption "unlocking possibilities". The advert was criticised as being "childish", so they decided to turn this criticism to their advantage by running a new advert showing a picture of a child holding a can-and-wire telephone to his ear. The caption read, "Curiosity without constraint, always exploring, always growing, youth isn't wasted on the young." So the criticism was turned into a strength, and made into a successful marketing campaign.

Stefan says, whatever we did we had fun. Life is short, and having fun with what you do is key.

9. Protecting shapes and colours: Trade Marks for MedTech

Robecca Davey

9. Protecting shapes and colours: Trade Marks for MedTech

A trade mark can be the most valuable asset of a business. When most people think of a trade mark they typically think of a word or a logo. But trade mark protection is not limited to words and logos. Protection can be obtained for shape, colour, motion, sounds, smells, tastes or even the texture of a product.

The ability to obtain trade mark protection for the shape and colour of distinctive products is of particular interest to the MedTech industry, where the shape and colour of medical devices is often of particular value.

Patents usually last for 20 years and registered designs for 25 years. Trade marks, on the other hand, have the potential to last forever and to provide the owner with monopoly protection of unlimited duration. For this reason, the value of a trade mark should not be underestimated, given the potential to protect the defining features of a product (for example, a distinctive shape or colour combination), long after patent or design rights have expired.

Indeed, we start below by looking at a trade mark which is still providing valuable protection more than 130 years after the original idea for the product, before looking at some examples of trade mark protection for the shapes and colours of products in the MedTech industry...

On May 8, 1886. Dr. John Pemberton, a local pharmacist in Atlanta, Georgia, USA produced a new syrup and carried a jug of the new product down the street to Jacobs' Pharmacy, where it was sampled, pronounced "excellent" and placed on sale for five cents a glass. During the first year, sales averaged a modest nine drinks per day.

The syrup’s formula contained coca leaf extract and caffeine from the kola nut. Thinking that "the two Cs would work well in advertising," Dr. Pemberton's partner and bookkeeper, Frank M. Robinson, suggested changing "kola" to "cola", and penned the now famous trade mark "Coca-Cola" in his unique, flowing Spencerian script lettering, with fanciful curls for the Cs.

Today there are a staggering 1.9 billion servings of Coca-Cola per day across 200 countries. As of December 2023 Coca-Cola had a market capitalisation of US $254.34 Billion, making Coca-Cola the world's 38th most valuable company by market capitalisation.

9. Protecting shapes and colours: Trade Marks for MedTech

Central and crucial to this success story has been the Coca-Cola trademark. A trade mark for Frank Robinson's flowing script version of Coca-Cola was granted in 1893. There have been various iterations of the logo since 1893, but it still remains similar to the original trade mark. According to Statista, in 2023 Coca-Cola's brand was valued at US $106.1 billion, placing Coca-Cola within the top 10 most valuable global brands.

Whilst many people are aware of the value of the Coca-Cola logo, fewer people are aware that Coca-Cola has been successful in registering the shape of Coca-Cola bottle as a trade mark.

The famous shape of the glass bottle was created in 1915. At the time bottlers worried that a straight-sided bottle wasn't distinctive enough and that Coca-Cola was becoming easily confused with 'copycat' brands. Glass manufacturers were approached to come up with a unique bottle design for Coca-Cola, which was introduced in 1916.

In 1960 a bottle with the word 'Coca-Cola' written on it received its first trade mark from the US Patent and Trademark Office. In 1977 the Coca-Cola bottle was granted a second trade mark for the contour shape itself, with no words written on it.

The ability to obtain trade mark protection for the shape of distinctive products is of particular interest to the MedTech industry, where the shape of medical devices is often of particular value, as we shall also consider in the next chapter on registered designs.

Whilst it has been possible to register a 3D shape or colour as a trade mark for many years now, the updates to the EU Trade Mark legislation in October 2017 (implemented into UK law in 2019) widened the scope of what is capable of being registered as a trade mark and has made it (in theory) easier than ever for brand owners to seek a monopoly over 'non-conventional' trade marks, such as motion marks, sounds, smells, tastes or even the texture of a product.

Amongst other things, the new legislation removed the requirement for a sign to be 'graphically represented' and replaced this with the requirement that a trade mark must

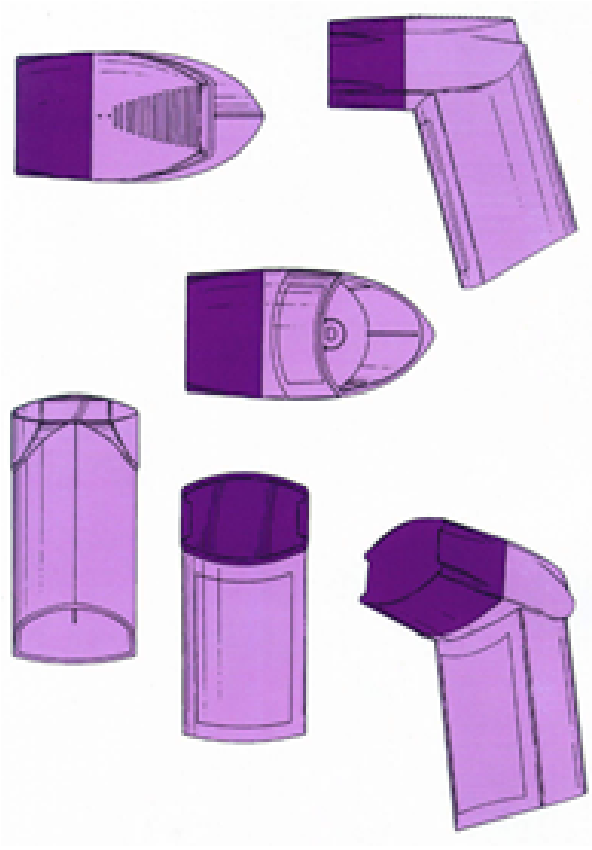
be ‘represented in the register in a manner which enables the registrar and other competent authorities and the public to determine the clear and precise subject matter of the protection afforded to the proprietor’. This change has had an impact on the types of trade marks that can be applied for and has resulted in some very interesting developments in case law.

Patents usually last for 20 years and registered designs for 25 years. Trade marks, on the other hand, have the potential to last forever and to provide the owner with monopoly protection of unlimited duration.For this reason, the value of a trade mark should not be underestimated, as seen from the example of Coca-Cola above, given the potential to protect the defining features of a product (for example, a distinctive shape or colour combination), long after patent or design rights have expired. In addition, trade marks are usually somewhat quicker and cheaper to register, compared to patents.

The value of a trade mark is something that consumer healthcare giant, GSK, are well versed in, and their trade mark successes and failures have been well documented in the news.

Over the years, GSK have registered (or attempted to register) a range of non-conventional trade marks for their products, including the two-tone colour combination for their asthma inhaler (the various views of which, as filed in their EUTM application, are shown on the right). Whilst this registration isn’t quite over the line yet (currently it is with the EU Board of Appeal following a Declaration of Invalidity filed against it by a third party), securing (and maintaining) registration of this colour mark would be a great asset to GSK – being able to potentially enforce their rights against others in the industry using this colour combination on goods covered by the mark.

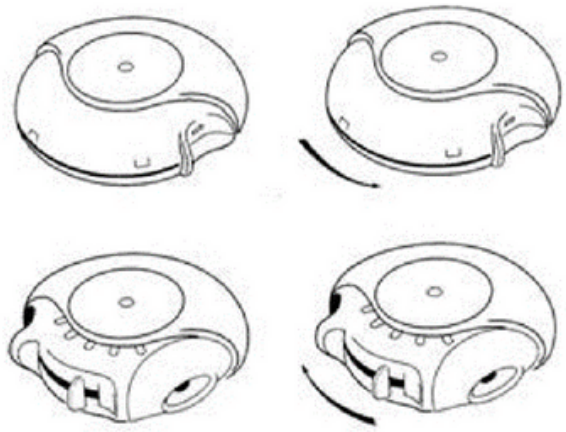
EUTM No. 002179562



9. Protecting shapes and colours: Trade Marks for MedTech

One of the trade mark registrations that GSK have managed to secure is the following shape of a circular asthma inhaler. Below are the views of the product submitted in the trade mark application:

EUTM No. 011131588



This mark was applied for on 21 August 2012 and achieved registration in October 2014 – so, fairly quickly for a 3D shape mark. That said, it has faced some obstacles in its route to registration, though thankfully for GSK, none of these was insurmountable.

After the filing of this application in August 2012, it met with objection under Articles 7(1)(b) of the EUTMR on the basis that it was considered to be non-distinctive (thus unable to perform the essential function of a trade mark – i.e. to identify the commercial origin of the goods / services and enable the consumer to repeat the experience if it is a positive one). The EUIPO went on to state that the features of the above depicted mark are 'not markedly different' from other shaped inhalers on the market. On this basis, the mark was refused in its entirety on the basis that it "cannot be sufficiently distinguished from other shapes commonly used for medical apparatus and instruments, inhalers, parts and fittings" and "will not enable the relevant public immediately and with certainty to distinguish the applicant / holder's goods from those of another commercial origin".This sort of objection is common, especially for 3D shape marks and, generally speaking, only shape marks which are considered to 'depart significantly from the norm' are considered to meet the threshold for registrability. This is partly because it is thought that consumers are not necessarily accustomed to seeing the shape of a mark as particularly 'origin-identifying' and instead are more likely to look to the brand name or logo to guarantee origin.

That said, GSK were determined to lock in registration of this shape mark and in October 2012, they filed a response to this objection. In their arguments they set out the unique nature of the shape in the field, and explained that no competitors were using anything the same or similar for such goods.The submissions went on to analyse each component part of the shape mark (the overall shape; the wave design, bisecting the device through the centre; the circle of top of the device; the mouthpiece; the slider; and the prongs) and the argument put forward was that the "functional components" of the device, i.e. the mouthpiece, slider, etc., are less likely to be paid attention to by the consumer, and are more likely to be taken for granted. Therefore, other elements of the device are likely to be given more weight, i.e. the unusual overall shape of the device, which they argued created a different overall impression and "departed from the norm" and therefore, should be considered sufficiently distinctive to achieve registration. Various examples of other branded inhalers were submitted as evidence to support these arguments, as well as extensive evidence of acquired distinctiveness.

Whilst the observations were taken into account, the objections raised were upheld and GSK filed an appeal against the refusals on both grounds. Ultimately, the decision against the representations of the marks contained in the application was annulled, however, the distinctiveness portion of the objection was maintained, and subsequently appealed to the Second Board of Appeal, where the objection was dismissed and the application allowed to proceed.

Whilst the written arguments that were filed (i.e. that the mark contained a combination of functional and non-functional elements and possessed at least the minimal amount of distinctiveness to achieve registration) may have assisted to get the mark though to registration, undoubtedly it was the large volume of evidence filed to demonstrate acquired distinctiveness of the mark that was pivotal in the allowance of this mark. Examples of evidence filed is set out below:

a. Details of the launch date of the inhaler in each member state of the EU.
b. Sale and advertising figures.
c. An image of the one brilliant inhaler.
d. Witness Statement from the Applicant setting out sales and market share information.
e. Sales figures for Europe in units and monetary value.
f. Awards in relation to the unique and innovative design of the inhaler.
g. Marketing materials.
h. Examples of packaging.
i. Information leaflets including information on distribution.
j. Survey evidence.

So the mark achieved registration and all was well until 2020 and 2021 when the validity of this registration was challenged, though in both cases the invalidity actions were withdrawn (leaving it open to question whether a settlement may have ultimately been agreed between the parties). The invalidity actions demonstrate the value of holding a shape mark registration, which could be licenced to third parties for use on products.

Overall, this story demonstrates the value of trade marks and the holistic approach that needs to be taken when planning an IP strategy, involving different types of IP where necessary. Trade mark protection should not be left solely for a brand name or logo, and can be an invaluable and long term way of protecting a product's shape and overall impression. As we saw from the example of Coca-Cola, a trade mark can still be providing extremely valuable protection more than 130 years after the original idea for the product!

10. Protecting aesthetic appearance: Registered Designs and MedTech

Greg Carty-Hornsby

10. Protecting aesthetic appearance: Registered Designs and MedTech

The aesthetic appearance of MedTech devices is often of key importance to their adoption by patients. As a result, modern medical device designers now talk of ‘human factors’ and ‘user experience’ as key philosophical tenants of the devices they design.

Patents generally cannot be used to protect the aesthetic appearance of products. Fortunately, aesthetic appearance can be protected by so-called "industrial designs", which are another type of intellectual property. Unlike patents, industrial designs specifically protect features of appearance, and can therefore be used to protect the visual elements of a product that contribute to its overall look and feel.

Industrial designs in the UK and EU come in both registered and unregistered forms. Registered designs provide longer lasting protection (up to 25 years following registration compared to a mere 3 for some forms of unregistered rights). Moreover, unlike patents, in the UK and EU registered designs undergo very little in the way of substantive examination. Due to their longevity and relative ease of acquisition, registered designs therefore represent an effective tool for the medical device designer looking to protect the look and feel of their products.

Unlike patents, registered designs can protect a wide range of non-technical attributes of a product, which includes, according to the Community Design Regulation EC 6/2002:

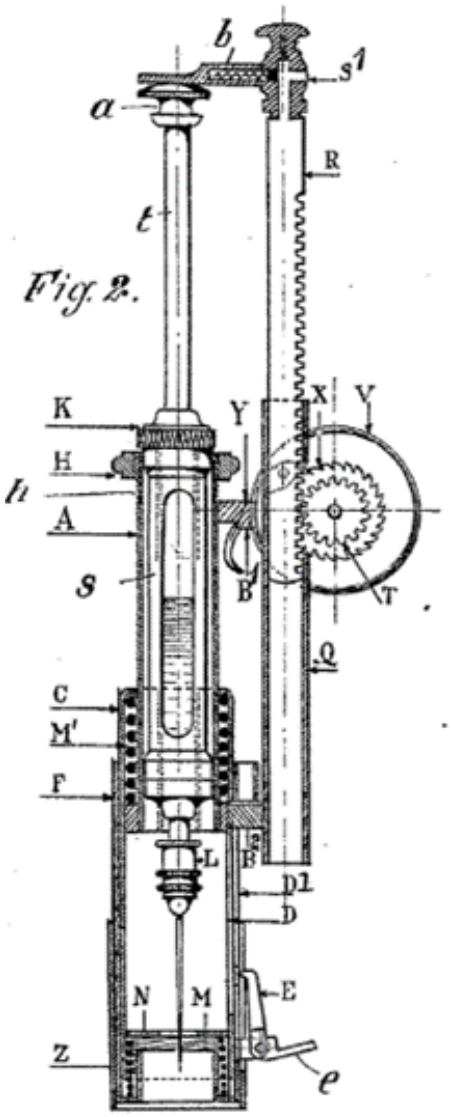
… the appearance of the whole or a part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture and/or materials of the product itself and/or its ornamentation.

Auto-injectors is a field where the aesthetics of the product can be particularly important for reassuring patients. Let's take a look at how registered designs have been used by a range of auto-injector manufacturers to protect their products...

In the days of the Cold War, the Soviet Union’s proliferation of new nerve agents generated a need for a battlefield-ready antidote. The United States had long known that various anticholinergic drugs could reverse the heart- and respiration-slowing effects of nerve agents, but only if delivered to the bloodstream quickly enough. Automatic drug injection devices had been around for a long time, having first been invented by Italian

doctor, Edmondo Luswergh, in the late 1910s (his patented device is shown on the right). However these systems were often complex and slow to deploy. There would be no time to deal with such complexities in the heat of the moment, and therefore a faster delivery solution was sought.

United Kingdom Patent 143,084 to Edmondo Luswergh (1919) [1]



Answering the call, in the late 1960s a company called Survival Technology Inc. duly developed a spring-loaded automatic injection device, known as the AtroPen®, for the rapid delivery of anti-nerve agent drugs to the human body. However, the AtroPen suffered from two main drawbacks making it unreliable on the battlefield.

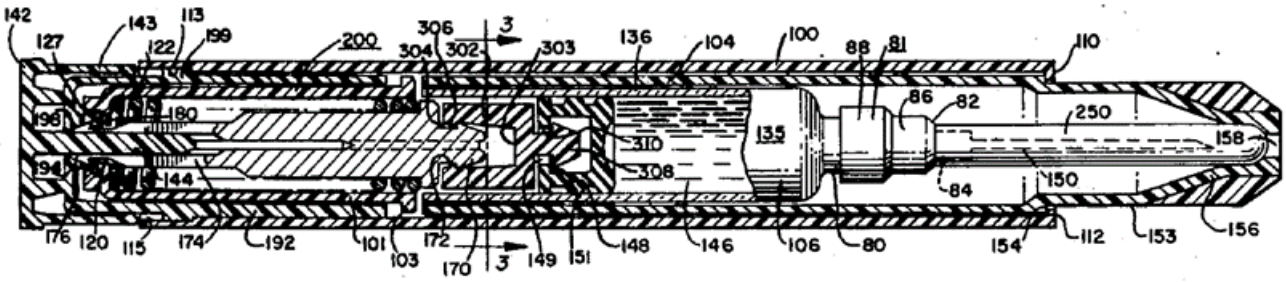
First, due to high vapour transmission rates, it could not be made from plastic. Therefore, the structural elements of the AtroPen were made from a mixture of stainless steel and glass. The latter of which is of course very fragile, and was prone to failure once the spring loaded delivery mechanism was released. Second, the use of stainless steel meant that the AtroPen could only be used with drugs that were stable when in contact with the metal elements of the device. This limited the range of drugs that could be delivered to a single one: Atropine.

Recognising the shortcomings of the AtroPen, mechanical engineer Sheldon Kaplan was tasked by Survival Technology Inc. to redesign the AtroPen to finally make it field-worthy. Previously, Kaplan had worked for NASA on the development of the emergency medical kits for the Apollo missions. Kaplan completely overhauled the AtroPen. Amongst other developments, Kaplan re-engineered the glass vial to cushion it from the action of the spring, and thereby dramatically improve the overall robustness of the device. The re-designed device was launched as the ComboPen, and issued to US military personnel around the world [2].

However, the story did not stop there. Kaplan had a colleague, Rick Toren, whose

daughter was severely allergic to bee stings. In order to protect his daughter, Toren had to carry around vials of the anticholinergic drug Epinephrine, to be delivered subcutaneously via hypodermic needle should his daughter ever be stung. Having seen Kaplan's success with the ComboPen, Toren had the idea that the system could be re-designed again, this time for use with Epinephrine. And thus, in 1975, the EpiPen® was born. Survival Technology subsequently patented it the following year, as shown in the image below.

US Patent 4,031,893 for Kaplan's EpiPen (1976) [3]



By borrowing features from that of the simple writing pen, the design of the EpiPen (shown below) is extremely intuitive. Most prominently, one end is shaped to form a tip indicating to the user that this is the side from which the needle is deployed. To deploy it, the user merely has to force the tip side against the recipient's body, whereupon the spring-loaded mechanism deploys the needle and delivers the drug. As a result, the EpiPen revolutionised emergency drug delivery and has saved countless lives. For his services to medical device design, Kaplan was inducted into the US Patent Office's hall of fame in 2016 [5].

EpiPen (pre-2016) [4]

Perhaps the most important development that the EpiPen provided was the realisation that the way in which the end user interacts with a medical device is a key component of the device's efficacy, and by extension of course also its commercial success. In particular, the shape and form of the EpiPen guides the user to interact with it in a

particular way, instinctively understanding which part to hold and which to deploy. Moreover, the overall clean and sleek form of the EpiPen is reassuring for patients, and indicates that this is a device engineered to do them good and not harm them. As a result, modern medical device designers now talk of ‘human factors’ and ‘user experience’ as key philosophical tenants of the devices they design.

Whilst technical developments to medical devices such as auto-injectors can be protected by patents (and indeed the EpiPen was subject to patent protection) there may be important aspects of a medical device that relate to its aesthetics. For example, most would surely agree that compared to Luswergh’s 1919 patent for the first auto-injector, the EpiPen has more eye appeal and presents a much less intimidating impression. Unfortunately, modern patent law excludes protection for aesthetic creations, as confirmed by Article 52(2) of the European Patent Convention, which states (to paraphrase):

The following in particular shall not be regarded as inventions:
discoveries, scientific theories and mathematical methods;
aesthetic creations;
schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
presentations of information.

Fortunately, aesthetic appearance can be protected by so-called "industrial designs", which are another type of intellectual property. Unlike patents, industrial designs specifically protect features of appearance, and can therefore be used to protect the visual elements of a product that contribute to its overall look and feel.

Industrial designs in the UK and EU come in both registered and unregistered forms, however registered designs provide longer lasting protection (up to 25 years following registration compared to a mere 3 for some forms of unregistered rights). Moreover, unlike patents, in the UK and EU registered designs undergo very little in the way of substantive examination. Due to their longevity and relative ease of acquisition, registered designs therefore represent an effective tool for the medical device designer looking to protect the look and feel of their products.

10. Protecting aesthetic appearance: Registered Designs and MedTech

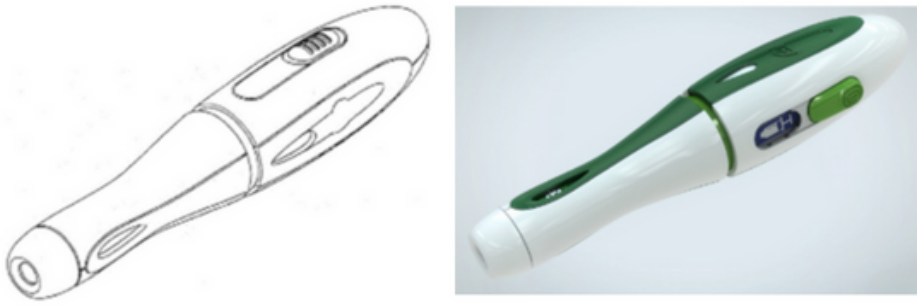
Design law in the UK and EU is relatively well harmonised, having been developed under a common system pre-Brexit. Unlike patents, registered designs can protect a wide range of non-technical attributes of a product, which includes, according to the Community Design Regulation EC 6/2002:

… the appearance of the whole or a part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture and/or materials of the product itself and/or its ornamentation.

Due to the value of aesthetics in medical device design, many modern auto-injector manufacturers employ registered designs to protect their products.

Returning to our story, auto-injectors are now used to treat a wide range of conditions, and are not limited simply to emergency situations such as anaphylaxis. For example, auto-injector technology is now used to treat chronic conditions such as multiple sclerosis (MS). These kinds of patients may be required to inject themselves with medicines several times per day, and may suffer from hand tremors making the handling of fine mechanical parts difficult to achieve. In order to service this particular group of patients, Swiss pharmaceutical giant Novartis launched the ExtaviPro® 30G auto-injector.

Novartis International Design D078547-0001 (left) [6] & ExtaviPro®30G (right) [7]



Similar to the EpiPen, the design of the ExtaviPro has a clearly identifiable injecting tip and an opposite, blunt, handle end. However, whilst smooth and streamlined, as compared to the EpiPen, the ExtaviPro is bulkier and has an almost bowling pin-like or nacelle-like shape. This is a deliberate stylistic choice, which strikes a balance between the reassuring appearance of slender lines and the need to provide a handle that is larger and more easily manipulable by a user with impaired hand mobility. As shown from the top left image above, Novartis has recognised the contribution of these stylistic

10. Protecting aesthetic appearance: Registered Designs and MedTech

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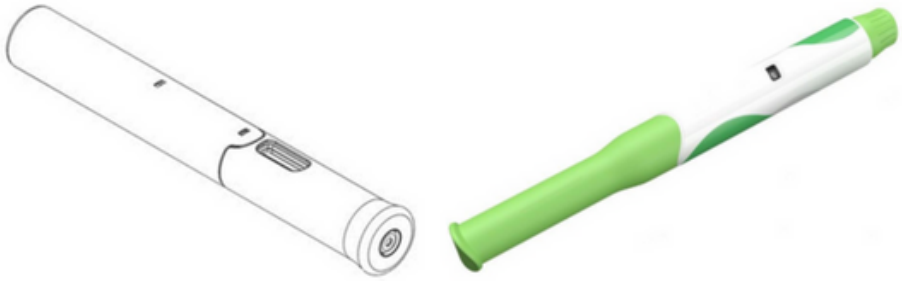
Other auto-injectors have been designed with versatility in mind, to enable them to be re-configured for the delivery of multiple different drugs. One such example, by the manufacturer Owen Mumford Ltd., is the Aidaptus®, which won a Red Dot design award in 2023. The Aidaptus contains a self-adjusting plunger to enable it to dispense different volumes of drug. Moreover, its deployment springs are replaceable, such that it can be used with drugs of varying viscosities. However, the Aidaptus also keeps to the traditional sleek cylindrical shape first used by the EpiPen.

Aidaptus® (2023) [8]

10. Protecting aesthetic appearance: Registered Designs and MedTech

In fact, many of Owen Mumford's designs employ sleek and slender lines, giving a clean and clinical impression to the devices, whilst shielding the needle from the patient to provide a non-threatening impression. Such is the commercial value of this aesthetic that Owen Mumford has obtained a number of design registrations across a range of different auto injectors, as shown below.

Community Design 015017097-0001 [9] and UK Design 6244791 [10] to Owen Mumford



In a similar vein, the PiccoJect (shown below), another Rod Dot winner, is a miniaturised auto-injector developed by Haselmeier GmbH of Germany. As the name suggest, the PiccoJect is designed to be as small as possible to as to be easily storable in a pocket or handbag. Due to its small size, the PiccoJect comprises a wraparound window that provides an easy means for the user to determine when delivery is complete. Again, the smooth shape of the PiccoJect provides a reassuring aesthetic to patients, which is complemented by the choice of a range of friendly colours, both of which would be suitable for protection under a registered design.

PiccoJect (2023) [10]

Thanks to Kaplan and the EpiPen, the auto-injector has come a long way from its rather functional-looking origins in the early 1900s to the devices that are available today. By placing the emphasis on usability and patient interaction, modern auto-injector design seeks to put patients at ease by incorporating a clinical aesthetic into products that form part of the users' everyday lives. Auto-injectors therefore exemplify not only the cutting edge of technical innovation, but also of stylistic design, and are therefore excellent candidates for protection under a range of intellectual property rights, including patents and registered designs.

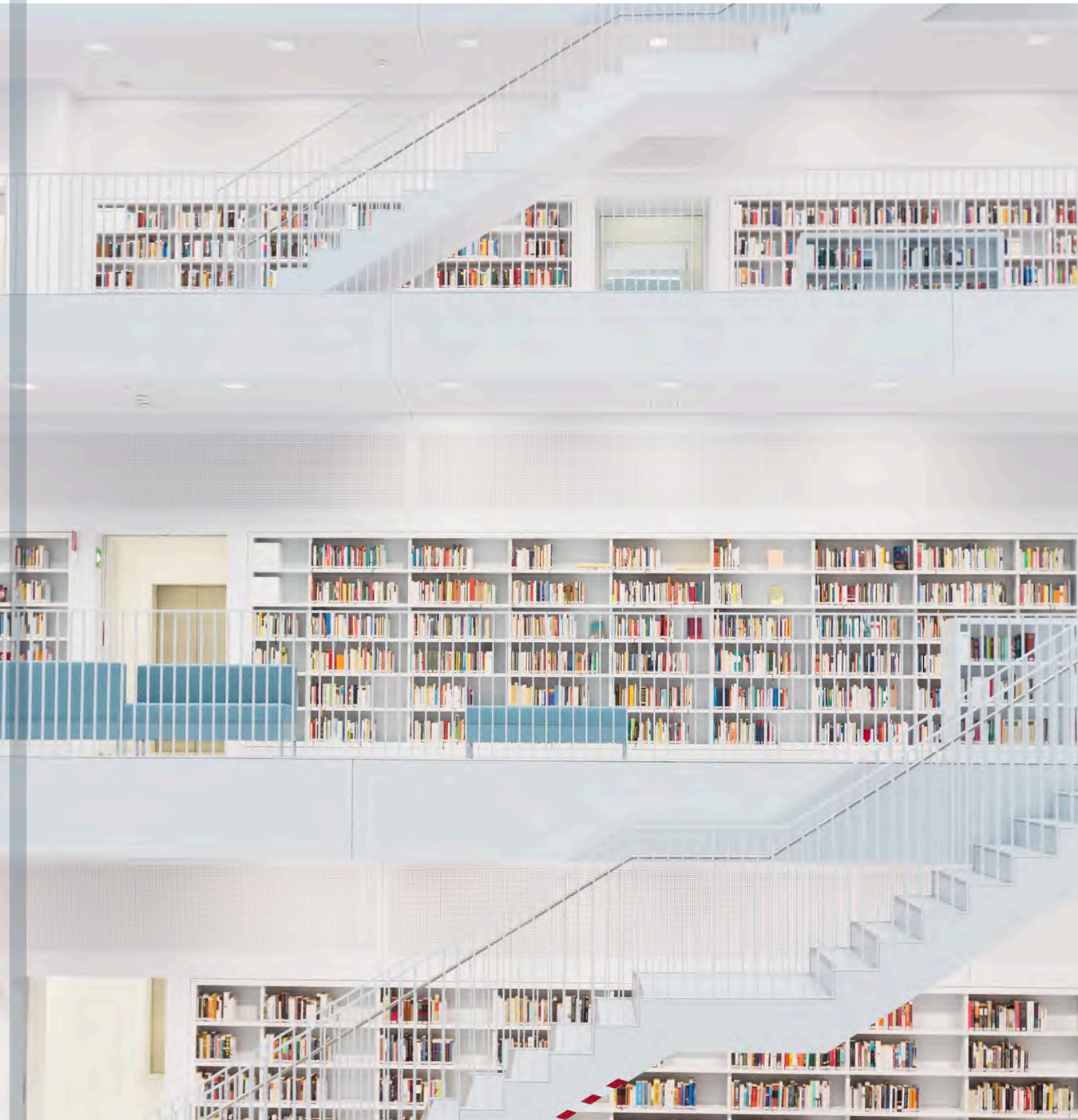
Chapter 10 references:

[1] GB 143,084 A
[2] https://news.northeastern.edu/2016/09/14/northeastern-alumnus-the-genius-behind-life-saving-epipen/
[3] US 4,031,893 A
[4] https://media.istockphoto.com/id/174530101/photo/epinephrine-auto-injector-pen-for-allergic-reaction.jpg?s=612x612&w=0&k=20&c=n5sE08ARFQuvtOa2fXIRBbSusnnSZv9yqqhjj4aVmN0=
[5] https://www.invent.org/inductees/sheldon-kaplan
[6] https://www.tmdn.org/tmdsview-web/#/dsview/detail/WO70000000D078547-0001
[7] https://www.cambridgeconsultants.com/sites/default/files/uploaded-images/Hero-Novartis-auto-injector-P1253-Magma.jpg
[8] https://www.red-dot.org/project/aidaptusr-65692
[9] https://www.tmdn.org/tmdsview-web/#/dsview/detail/EM700000015017097-0001
[10] https://www.tmdn.org/tmdsview-web/#/dsview/detail/GB702023006244791-0001
[11] https://www.red-dot.org/project/piccojecttm-64042

MedTech IP

Lessons and strategies for success

Appendix



Appendix: Table of MedTech areas / details discussed

Chapter	Individual / inventor discussed	Companies discussed	Patent application filed	MedTech area
1. Keep innovating: The remarkable story of ResMed	Colin Sullivan	ResMed Ltd	1981	CPAP (Continuous Positive Airway Pressure)
2. Don't take "No" for an answer: Surgery and diagnosis	Martin Prince	n/a	1997	MRI injections
3. Keep your vision clear: Therapeutic methods	Josef Rodenstock	Rodenstock GmbH	2001	Progressive spectacle lenses
4. Push the boundaries: Computers and MedTech	Melbourne J. Hellstrom	Koch & Sterzel GmbH	1978	X-ray apparatus
5. Fortune favours the brave: Computer-assisted methods	Stefan Vilsmeier	BrainLab AG	2014	Surgery / positioning a medical structure
6. Let the heart rule: AI and MedTech	Teuvo Kohonen	Cardionics Limited	1996	Heartbeat monitoring apparatus
7. Don't be afraid to burn the midnight oil: Additive Manufacturing and MedTech	Chuck Hull	Siemens Healthcare GmbH	2015	Personalised heart vessel stent
8. Strategies for success: The remarkable story of BrainLab AG	Stefan Vilsmeier	BrainLab AG	n/a	Surgery / medical video games
9. Protecting shapes and colours: Trade Marks for MedTech	Dr. John Pemberton	Coca-Cola GSK	n/a	Asthma inhalers
10. Protecting aesthetic appearance: Registered Designs and MedTech	Edmondo Luswergh; Sheldon Kaplan	Survival Technology; Novartis; Owen Mumford; Haselmeier	n/a	Auto-injectors

Appendix: About the authors

Julian Asquith, Partner
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Julian is a Chartered and European Patent Attorney with extensive experience of patents and designs around the world.

He has worked with clients of all sizes, from individuals and start-ups to some of the world's largest companies, and has experience of all areas of drafting, prosecuting and advising on patents, including hearings at the UKIPO and oral proceedings at the European Patent Office in patent prosecution, oppositions and appeals. Julian has worked with clients in a large range of technical areas, including electronics, software, semiconductor devices, medtech, telecommunications, energy, and a wide range of engineering fields.

Julian graduated from the University of Oxford with Honours and Masters degrees in Physics. After qualifying in the patent profession in the UK, he spent four years working for a major patent attorney firm in Australia, where he qualified as an Australian patent and trade mark attorney. On returning to the UK, he became a partner of the firm in 1997, and later served on the board of Marks & Clerk International.

Julian has been a member of the Council of the European Patent Institute (epi) since 2017 and has served as a member of the Council of the Chartered Institute of Patent Attorneys (CIPA). In 2017 Julian was elected as a member of the ICT group of the epi European Patent Practice Committee and is a member of the CIPA Computer Technology Committee. He has published articles in a range of publications, including the CIPA Journal and epi-Information, being the publications of the institutes for Patent Attorneys in the UK and before the European Patent Office (EPO).

Julian is listed in Legal 500 as "highly recommended".

Appendix: About the authors

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Robecca is a Chartered Trade Mark Attorney and Senior Associate in the trade mark team. Robecca focuses her practice on national and international trade mark law, including dispute matters, negotiation of settlements, brand clearance and searching, and the worldwide prosecution of trade mark portfolios.

Robecca acts for a broad spectrum of clients ranging from large multi-national companies to start-ups and individuals, in a range of industries including fashion and luxury, finance, cosmetics, food and beverage, sports and technology, fast moving consumer goods and pharmaceuticals.

Prior to joining Marks & Clerk, Robecca worked for a global law firm where she qualified as a Chartered Trade Mark Attorney in 2018, passing the Professional Certificate in Trade Mark Practice (PCTMP) at Nottingham Trent University. Prior to this, Robecca successfully completed the postgraduate certificate in Trade Mark Law and Practice at Queen Mary, University of London.

Robecca lectures on the CITMA paralegal course and has also contributed to The CITMA & CIPA European Union Trade Mark Handbook by updating the trade mark invalidity/revocation chapter.

Appendix: About the authors

Greg Carty-Hornsby, Partner
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Greg's patent work focusses on mechanical technologies across a range of industries including medical technology, automotive, manufacturing, food and beverage production, and printing. He has extensive experience drafting and prosecuting patent applications in the UK and Europe, as well as co-ordinating prosecution abroad.

Greg often works on contentious matters. He has extensive experience in oppositions and appeals before the European Patent Office (EPO), often against the backdrop of co-pending litigation. He has also acted in, and continues to handle, revocation matters before the Unified Patent Court (UPC). Greg is frequently involved in clearance work for many of his clients, advising on matters of infringement and validity across a range of jurisdictions. Greg has international experience of patent prosecution and clearance matters, having been seconded to our Hong Kong office in the support of an existing client.

Appendix: About Marks & Clerk

Marks & Clerk set up its first office in the UK in 1887. Today, we're a leading global intellectual property firm, working in partnership with businesses of all shapes and sizes all over the world. Providing them with people whose legal, technical and commercial expertise exactly meets their needs. Shaping our services around them. Protecting, enforcing and maximising the value of their intellectual property to support them in achieving their business ambitions.

Multidisciplinary teams working to get the very best result for you

Many of today's medical technology products involve more than one technology, and traditional MedTech markets are being disrupted by emerging technologies such as AI, extended reality and 3D printing. Because of our size and spread of expertise, we can assemble a team of people with extensive knowledge in each of the relevant technologies. Our people are experienced at coming together in teams and working to get the very best result for you.

Complete IP service

In addition to our patent attorneys and trade mark attorneys, we have a large team of commercial lawyers. They become part of the team where issues such as freedom to operate arise or contracts are required.

Our patent attorneys have a wealth of experience in EPO oppositions and appeals and, together with our skilled IP litigators have a very high success rate in the courts in clearing the way for businesses to enter the market. Before any action is taken, we carefully analyse legal and commercial circumstances and give you clear advice on the cost and the chances of success, enabling you to make a confident commercially-based decision. Marks & Clerk have often succeeded with cases that others have been unable to resolve.

Clients

For many decades, Marks & Clerk has worked with a large number of medical technology businesses. They range from large corporates to fast growth SMEs and operate across all parts of the world.