Royal Australasian College of Surgeons

The challenge of patenting a new medical device

Introduction

As practising surgeons, we all lament at times deficiencies in current medical equipment or devices. Only a small percentage of us however are prepared to tackle the deficiency and take that major step of putting our inventive ideas into practice to try to correct the deficiency. Transforming a good idea into a commercial product is extremely challenging and obtaining a patent is often an important consideration in making the project financially viable.

The problem to be solved

One of the most frequent and frustrating consults that urologists face is the difficult catheterisation of a male patient, particularly after previous TURP or instrumentation.[1] The problem is usually due to either a 'false passage', caused by urethral trauma to the upward curved segment of the bulbar urethra, or the presence of a 'lip' under the bladder neck after a previous TURP. House doctors have been utilizing coudé tip catheters for years, and often the hockey stick shaped fixed upward curve of the catheter tip allows the catheter to bypass the level of hold-up. However, even these catheters are often inadequate, and usually a urologist or urology registrar is then called to facilitate the catheterisation by using a rigid, steel catheter introducer, also shaped like a hockey stick, and inserted into the catheter to enable manipulation of the position of the catheter tip within the urethra. These introducers are however inherently dangerous to use, and in inexperienced hands can cause major urethral trauma, and for that reason, most hospitals restrict their use to urologists or urology trainees, who have learnt to use them in theatre with the patient under GA, and with the backup of a cystoscopy if the catheter doesn't pass easily.

Discussion

After years of contemplation, by 2019 the principal author (ISM) had come to the conclusion that if a coudé tip catheter could be developed, the tip of which could be actively deflected to the angle appropriate for the particular urethra causing difficulty, then the success rate for catheterisation could potentially be increased significantly. The first author, a busy practising urologist, discussed the idea with his two medical practitioner sons, and the three of us decided to jointly pursue the idea and determine if it was patentable and could be the basis for the development of a new and useful type of urethral catheter. The idea involved incorporating into the catheter a steering wire or filament, based on the broad principle used in most flexible endoscopes, but designed in such a way that the mechanism would be simple, cheap to produce and disposable (Figure 1).[2] A cursory Google review of the literature did not bring up any references for a urethral catheter with an actively deflectable tip, although we knew that if we wished to pursue the idea with a view to eventual commercialisation, a professional patent search would be required.

We then made an appointment to meet a professional patent attorney. The initial consultation was free, but the lawyer made it pretty clear from the start that obtaining even a single patent in a reasonable number of countries would be time-consuming and expensive, and there would be no guarantee of actually being granted a patent anywhere. The attorney said that patents always took years to obtain, and when pressed for a cost estimate, suggested a figure of $A100,000 would be typical for an uncomplicated patent registered in perhaps six countries. The lawyer explained that most of this figure would be legal fees rather than statutory costs. The legal charge-out rate would be over $A500 per hour.

Although a daunting prospect, we decided that the catheter concept was worth pursuing, and that we would at least embark on the journey. We also committed to each other that we would terminate the process if at any stage it became clear that the idea was not unique and therefore unlikely to be patentable, or if the costs became so great that the potential benefit was not worth the financial commitment. While it may be possible to enlist other sources of finance such as government grants, private investors or tech incubators during commercialisation, we found this was not possible during the patenting process alone. Our patent attorney confirmed that this is almost always the case.

The initial process involved our patent attorney contracting a specialist patent search attorney colleague to perform a comprehensive patent search to locate any current patents which appeared to overlap significantly with our idea. About 6 weeks later, the attorney came back with several patents for urinary tract catheters which had some steerability, although none which had been specifically designed to negotiate the urethra itself. While the search was underway, the three inventors were refining the concept and drawing and sharing multiple draft diagrams of possible configurations, taking into account possible impracticalities which might be encountered during the development of prototypes. At this time, our first invoice of many subsequent invoices was received and paid. One of the benefits of being a team was that at least some of the costs were shared.

After our group had reviewed the possible conflicting patents discovered by the 'search' patent attorney, and in consultation with our primary patent attorney, it was decided that our ideas were

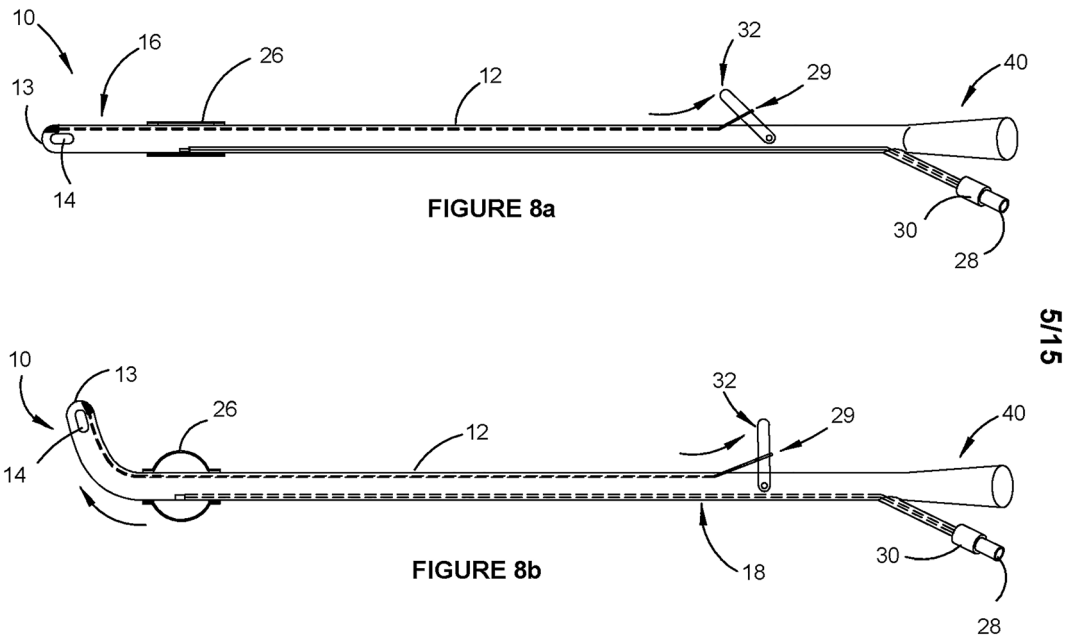

Fig. 1. A diagram of the catheter deflecting mechanism, taken from our original patent specification.

potentially unique enough to qualify for a patent. As soon as a decision was made to pursue a patent, our patent attorney produced for us a standard non-disclosure agreement (NDA) form, a copy of which we had signed by any individual with whom we shared details of our invention, prior to that disclosure. An NDA was signed by every member of the MDPP team (see later).

It is important for inventors to understand the importance of not publicizing their ideas before a formal patent application is complete and a priority date is established. This may be particularly difficult for academics who need to publish to survive, but any prior publication of the details of their work may nullify any chance of that idea being accepted as 'inventive' when a patent application follows. Some countries, including the USA, do allow a period of grace of up to 12 months after a publication, but most do not. All employees should also check their work contracts for any entitlement of their employer to claim the rights to any IP developed by the employee during their employment.

Once we had sketched some rough diagrams which incorporated all our main ideas for the proposed new catheter and as many variations as we could imagine, we started to formalize a description of the catheter, with emphasis on those features which made it unique compared with other catheters which had already been described. We did as much of this as we could ourselves, but it was clear that our layman's description would have to be put in 'legal speak' by our patent attorney.

The lawyer also contracted a graphic artist to formalize all our draft sketches into professional-quality drawings. Concurrent with drafting diagrams of our potential catheter, we experimented by modifying existing catheters in a rudimentary fashion, to test our initial ideas and possibilities. It was however not possible to really assess the practicality of our theoretical design, until we had professional assistance with the production of genuine prototypes (see later).

The specification

The basic description of an invention is called the 'specification'. This is divided into a number of sections[3]:

(1) **The title of the invention.** In our case, the formal title was "Urinary catheter and method of catheterisation using an actively deflectable urethral catheter and a deflection mechanism."

(2) **Background.** A detailed description of the new device, including the reasons for the need for the new device, the design itself, materials used and how the device is actually used. Mention may be made in this section of other related devices which may have been located in the search, with an explanation as to why the new device differs from previous devices, and how those differences may prove advantageous. Mention is made of all the envisaged possible variations in the design, so as to broaden as much as possible the potential scope for future inclusions.

(3) **Summary of invention.** A more succinct summary of Section 2.

(4) **Brief description of the drawings.** If there are drawings in the specification, each figure must be numbered in sequence, and a brief description of each figure is listed. The actual drawings are inserted later in the specification, and usually together rather than inserted between text. In our case there were 27 separate drawings, which included some anatomical diagrams showing the actual insertion of the catheter.

(5) **Detailed description.** A very detailed description of every component and function of the device, including reference to particular figures and reference numerals.
(6) **Reference numerals.** Components of the new device must be numerically labelled in the drawings, and reference numerals are listed and the component named in what is essentially a legend for the drawings.
(7) **Abstract.** A brief, one-paragraph summary of the new invention.
(8) **Claims.** This is the critical part of the specification. In this section, critical features are listed which make the invention different in some way from all previous inventions which have been patented. For a patent to be granted, at least one feature of the new device must be assessed by the patent 'examiner' to be 'inventive'.
(9) **Figures.** All the drawings. In general, photographs and colour are not allowed.

Internationally regulated, there are very specific rules regarding all aspects of the specification and what must be included, what can be included and exactly how it has to be documented. These rules include acceptable fonts, spacing, size of print and page labelling. Each section must be included in sequence and drawings appropriately labelled. While maximum details and scope are important, an excessive number of pages will cost more to register, and an excess number of claims may result in a significant cost penalty. Each country has its own regulations regarding the number of claims which can be included in the base cost and claims in excess of this number will attract an additional fee.

While it is possible for an individual to apply for a provisional patent in Australia without utilizing the services of a patent attorney, the complexity of the process and regulations makes this option a potentially very difficult and frustrating alternative. In our case, we did submit a second provisional patent application ourselves, but this was for the same device, and just contained some minor additional variations to those documented in the first patent, and it was thus possible to use most of the text and diagrams from the first patent application. Once the applications reach the 'national phase', and submissions have to be submitted to IP regulators in other countries, the use of a local attorney to contract an international patent attorney in each country of application, becomes virtually essential.

Patent jurisdictions

The patent process in our case involved three basic stages, although it is possible to bypass one or both of the first two stages:

(1) Application for a provisional patent.
(2) Application for an International patent under the Patent Co-operation Treaty (PCT). (The International Phase).
(3) Application for National patents for individual countries. (The National Phase).
(4) Once the draft specification is corrected, modified as necessary and accepted by the contributors and the patent attorney, it is submitted by the inventors or the patent attorney to the intellectual property body of the country in which registration of the provisional patent is desired. In our case, the provisional patent application was submitted to Intellectual Property Australia (IPA) and registered on 16 September 2019. Once the new provisional patent is registered, the date of that registration is locked in and from then on is known as the 'priority date'. The date and time of registration will be recognized internationally, and any patent applications submitted in co-operating countries after that date, will have a later priority date. If any of the content of the earlier submitted application is subsequently accepted for patent, the content of that application will have priority for acceptance. If there is an overlap in the claims for a particular invention, any so called 'prior art' may negate the inventiveness of the subsequent application.
(5) Once provisional patent registration is confirmed, an application for a standard national patent or alternatively an application under the Patent Co-operation Treaty must be made within 12 months. In our case, we deferred applying to any individual countries and applied under the Patent Co-operation Treaty to the World Intellectual Property Organization (WIPO). 157 countries are signatories to this treaty, and applying under PCT allows the priority date to be recognized in each of those countries pending formal application to individual countries later. Individual country applications must be made within 31 months of the priority date, or else the priority date is forfeited.
(6) Between November 2021 and March 2022 we converted our PCT application to National applications in the following countries/continents:Australia, New Zealand, Canada, USA, Japan, China, India and Europe.

Each of these applications required our Australian patent attorney to liaise with a colleague in the designated country, and in China and Japan also required the engagement of a legal translator to have the application prepared in the local language. Each local attorney charged significant fees for the application, in addition to the fees charged by our Australian attorney to liaise with them.

Patent application examinations

At each stage of progression examination of the patent can be requested by the applicant, but examination is mandatory in the National phase before an actual patent will be granted. The examination involves an assessment of the specification by a specialist in the IP Department of the country to which the application has been made, including a comparison of the invention with any previously patented similar invention. A search of the patent literature will therefore be necessary before an examination can be performed. In some jurisdictions such as the USA, the wait for an examination in the National phase can be over 2 years after the request is made.

Examination in the provisional or PCT phase will give the applicant an idea of the potential patentability of the invention, but a favourable report carries no status regarding an actual patent. Amendments are possible during each of the examination phases but can only involve changes which do not increase the scope of the specification. For example, the original specification may state that a particular component may be made of plastic. For clarification purposes, and perhaps to distinguish the specification from

another competing application mentioned by the examiner, an amendment may include which particular types of plastic may be suitable but may not state that the component may also be made of metal. An amendment may therefore be more specific but not broader in its coverage.

The main focus of any examination will be the claims. Different jurisdictions will have different requirements and rules regarding what is allowed. In Australia, there is a significant financial penalty for each additional claim over 20 claims, whereas in New Zealand, 29 claims are allowed before there is an additional fee. In Europe, claims are allowed which include details of the physical features of a new medical device, but a description of the way it is actually used is not allowed. As an example, in our Australian application, we were allowed to describe not only the physical characteristics of our new catheter, but also the particular technique that should be utilized to insert it into the urethra. In our European application, we were allowed to include the former in our claims, but not the latter.

In the final analysis, the examiner will assess each claim and categorize it as having any or all of:

(1) An inventive step.
(2) Novelty.
(3) Industrial applicability.

After the examiner's initial report, there is usually much jockeying back and forth, e-mail discussion of the other comparable inventions and modifications/amendments as necessary. The examiner will then issue a final report. To obtain a definitive patent, the final examination report on an application in the National phase must contain at least one claim which is regarded by the examiner as representing an inventive step. The difference between an inventive step and just a novel step is clearly somewhat subjective, but the applicant will likely need to argue that a claim represents quite a new concept rather than perhaps just an extension or progression of a current patented idea.

In our initial application, we included 13 claims. We requested an international search in June 2020 and we received the initial examination report in July 2020, which listed 21 other international patents with potential conflicting prior art and classified 6 of our 13 claims as novel but none as inventive. For the next 12 months we communicated back and forth with the examiners, attempting to explain the differences between our device and all those listed in the prior art, but particularly concentrating on four other patents with genuine similarities to the structure or function of our catheter. During that phase, and to help distinguish our device from previously described devices, we added an additional 20 claims. These additional claims allowed us to be specific about some of the characteristics of our catheter but did not allow us to increase the scope, that is, to claim characteristics which were not included in the original patent specification.

In July 2021, we received the examiner's final opinion regarding our application under the PCT, and the assessment was that:

33 of 33 claims involved an inventive step.
33 of 33 claims were novel and.
33 of 33 claims were industrially applicable.

While this report did not grant us a patent in any jurisdiction, our patent attorney advised that a positive report would be viewed positively by the examiner in each of the applications in the national phase. This proved to be correct in the first three jurisdictions examined, and we were granted our first full patent in July 2022 in Australia. Subsequently, we have also been granted patents in Canada and New Zealand. Examination in each of the other five jurisdictions is pending, but we have now paid an additional fee to have our US examination expedited, as our attorney advises us that the USA is regarded as the most difficult jurisdiction, and being granted a patent there is viewed very favourably by other jurisdictions. This might potentially result in fewer objections in some of the other jurisdictions, and less delay and cost.

Other considerations

Immediately following our initial application for a provisional patent back in September 2019, our group had intensive discussions about any other possible variations which we should include in a potential second patent application. Because there is always an imperative to get a priority date as soon as possible, there is no doubt also a high probability of subsequently having new ideas which have the potential to enhance the likely commercial success of the new invention. Once submitted, there is little if any ability to amend the application to widen its scope (as stated above), without the necessity to lose the initial priority date. Our group certainly had a flood of new ideas for possible modifications, which resulted in us submitting an application for a second patent only 3 months after the first, to include a number of these possible variations, the utility of which we knew would perhaps only become evident after the production of some prototypes.

At various stages during the examination process, patent applications will be published in full, and thus the details become public knowledge, and the necessity to maintain the earliest possible priority date is even more essential.

Another consideration with any new device for which commercialisation is planned, is the registration of a trademark. Our group voted for RLM to have responsibility for registering a trademark for our new device. After considering a number of alternatives, we decided on the trade name 'DeflectaCath' (Figure 2).

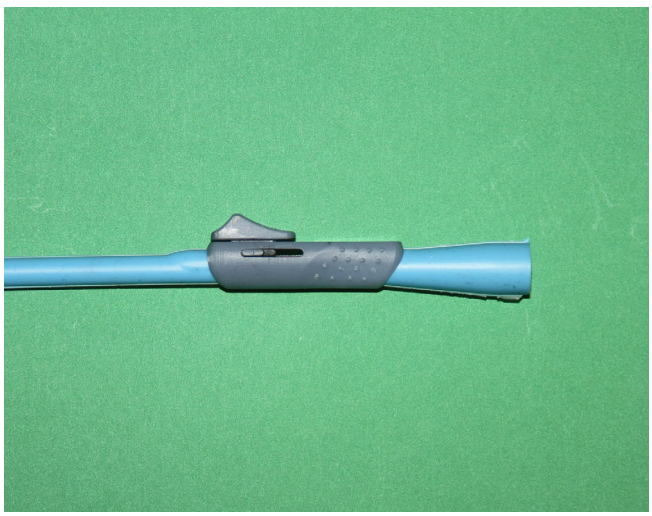

Fig. 2. The final prototype deflector mechanism of the DeflectaCath.

Fortunately, this process was relatively easy and inexpensive, and did not require the involvement of our patent attorney, and the trademark was accepted on 17 January 2021.[4] In cases where the device is not patentable or it is considered that proceeding to a full patent will not be cost-effective, consideration can be given to obtaining a trademark alone.

It is now just over 5 years since our initial meeting with our patent attorney to first discuss developing and patenting our idea for a new medical device. Even now we only have patents in three of the eight planned jurisdictions and anticipate that examinations in all the jurisdictions will take at least another 12 months. The initial cost estimate of our patent attorney has proven reasonably accurate so far, and we will potentially end up paying double that amount if we proceed to a full second patent in each of the jurisdictions. We have already had to apply in the national phase for each jurisdiction for our second patent application, to comply with the time limit after the priority date of December 2019.

The decision to proceed with an application for an international patent cannot be taken lightly. The inventor must have at least a reasonable expectation that the new device will be useful and provide a function not already available at a comparable cost. Most of the costs documented above are unavoidable, although a decision may be made to seek protection in only a small number of jurisdictions, depending on the likely market for the device in question. Enormous patience and obsessive attention to every minor detail is required. The principal author currently has 1127 emails in the patent email inbox alone, and there will no doubt be many more communications necessary before the process is complete for all the applications just for the first patent.

There have so far been 139 separate invoices for intellectual property alone.

Discussion of the potential commercialisation of a medical device could be the subject of another paper, however, it was clear to us early in the process that obtaining a patent alone does not guarantee any commercial benefit. Our group was fortunate to be selected by a competitive application process to have the development of our device facilitated by the Medical Devices Partnering Programme. This is a government-subsidized unit based at Flinders University in Adelaide which is staffed by a number of business and engineering specialists who take on specific projects to help inventors of new medical devices get to the next stage towards commercialisation. In our case, for a relatively nominal fee of $A5,000, we received business and IP advice, but more importantly, were lucky to be teamed up with a very enthusiastic and innovative engineer, John Nicholl, who developed a working prototype which we plan to take to current catheter manufacturers in the hope of developing a business relationship and a pathway to production.

Conclusion

The process of obtaining a patent for a new medical device is time-consuming and expensive and requires great patience and persistence. There is no guarantee that even a very good and apparently unique idea will be supported by the patent authority to be granted a patent.

Disclosure statement

The authors are the inventors of the medical device which is the example used to illustrate the difficulties experienced when trying to patent a medical device and are thus the potential beneficiaries if the device proceeds to commercialization.

Author contributions

Ian S. Middleton: Conceptualization; project administration; visualization; writing – original draft; writing – review and editing. **Rory L. Middleton:** Conceptualization; visualization; writing – review and editing. **Dougal L. Middleton:** Conceptualization; visualization; writing – review and editing.

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Ian S. Middleton,* FRACS (Urol.)
Rory L. Middleton,† MBBS
Dougal L. Middleton,‡ MD, BSc (Physio.)
Department of Urology, Royal Hobart Hospital, Hobart, Tasmania, Australia, †Department of Plastic and Reconstructive Surgery, Western Health Foundation, Sunshine, Victoria, Australia and ‡Department of Orthopaedics, Cairns Base Hospital, Cairns, Queensland, Australia

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