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Review

Surgeons produce innovative ideas which are frequently lost in the labyrinth of patents☆

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Summary

Thoracic and cardiovascular surgery are innovative specialties that regularly recruit the latest technological developments into their armoury of devices and equipment. The introduction of new technology is dependant on patents; an important but single component of intellectual property. Patents enable the attribution of rights to concepts, ideas and inventions and this facilitates ownership, subsequent licensing and overall management of innovation and its outcome. It is not just thoracic and cardiovascular surgery, but the healthcare world in general that experiences ongoing technological evolution; so to remain contemporary, it is important that those in positions of responsibility are familiar with the relevant processes. This requires basic medico-legal knowledge and may be entwined with significant financial responsibility. Penetrating clinical, academic and industrial environments, informed awareness of patents also contributes to important leadership skills, encouraging the incorporation of innovation into the professional milieu. We aim to present through this manuscript an overview of these issues in order to promote awareness of patents within thoracic and cardiovascular surgery using a descriptive and practical approach.

Keywords: Patents; Ownership; Industry; Commerce; Conflict of interest/economics; Surgical procedures; Devices

1. Introduction

Patents, a single but essential component of intellectual property, provide the means through which devices, instruments and equipment can be protected. Multiple levels of protection exist such as proprietary manufacturing technology and combinations of these can strengthen the degree of protection. Without patents, devices cannot enter the marketplace without exploitation risk and the owners of the devices who may be individuals, universities or hospital trusts may not benefit from their potential.

Any specialty that attracts regular recruitment of up-to-date technology, needs a foundation of understanding of patents and intellectual property. Thoracic and cardiovascular surgery are examples of surgical specialties that depend on the use of an extensive array of devices and technology. This is to support the requirement to remain at the forefront of contemporary surgery such that the best possible healthcare facilities can be delivered. By definition, to remain contemporary necessitates a continuous process of development and adoption of evolving technology.

Inventions need to meet specific criteria to be eligible for a patent which is '... a contract ... that grants the patent holder the right to exclude others from making, using, or selling the invention for a period of 20 years from the date of filing of the patent application' [1].

Patents and their management have inherent advantages and benefits. One of the most important benefits of patents is the generation of positive financial return but they themselves cost money to initiate. Significant revenue may be generated for the individual, academic organisation and hospital trust. Patents are now recognised as a professional activity by academic surgeons and may contribute to their formal assessment. Successful patent applications also demonstrate evidence of clinical governance adherence since they can be used for the purposes of re-validation and self-appraisal. The potential intellectual recognition and political gain all contribute to the enhancement of professional reputation and recognition. Finally, an important function of patents is that they facilitate the dissemination of technical and scientific information.

Merging the clinical world with intellectual property and patents has its disadvantages. Even though there ultimately

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may be generation of revenue, patents are burdened with significant financial responsibility, especially in the early stages. For this reason, surgical progress often requires industrial support and clinicians and surgeons need to be included in these negotiations. Union with the industry may introduce restrictions on the inventors. The time commitment required is significant and may impede on the clinician's time management balance. It is well recognised that even armed with prior knowledge, the time consumed through a patent application is significant, let alone committing further time to studying the process. Acquiring an understanding of patents and their legislation is intellectually demanding and challenges include coping with complex geographical variations and delicate ethical quandaries.

It is a predictable consequence that the same professionals that utilise novel technology are often the creators of the concepts and ideas but they often risk losing 'ownership' and intellectual property rights in the 'development to manufacture process' and consequently losing out on the possible benefits. This may be a result of lack of familiarity with the processes and potential exploitation by the industry. Though familiar with the basic concepts of patents, thoracic and cardiovascular surgeons and clinicians in general may not be comfortable with the mechanics of their implementation and furthermore, the experience of 'patent life' can vary significantly with geographical change. It is concerning that apprehension of the unknown and avoidance of ethical dilemmas may discourage an attitude of innovation and the development of novel ideas. This may lead to a negative impact on the growth of the specialty at a most critical time when it is established that the face of thoracic and cardiovascular practice must change to adapt to the current era.

2. Terms for understanding intellectual property emphasising patent management

Patent administration integrates many aspects including an extensive legal framework. Many of the terms used will be unfamiliar to those with no legal or commercial background. To begin to understand the practise and management of patents, even in basic terms, it is essential to comprehend the language and terminology. A glossary of essential terms and definitions are presented in Table 1 to facilitate this understanding and abbreviations are shown in Appendix A.

Table 1
Definitions and key terms in intellectual property.

Invention	An invention is a new (previously undiscovered) method, device, process, algorithm, or tangible material that can be used for a specific purpose [Duke University].
Inventor	The inventor is the person who thinks of the invention.
Owner and ownership	Ownership is the state or fact of exclusive rights and control over property, which may be an object, land/real estate, intellectual property (arguably) or some other kind of property [Wikipedia].
Trade secret	'Trade secrets' are non-patented confidential ideas.
Innovation	Putting the idea into practice.
Copyright	A copyright is the exclusive legal right, given to the originator or their assignee for a fixed number of years, to publish, perform, film, or record literary, artistic, or musical material, and to authorize others to do the same [Oxford Dictionary].
License	System through which the owner of intellectual property enables another person or company to use the intellectual property.
Trade mark	A trade mark is a symbol, word, or words, legally registered or established by use as representing a company or product or a distinctive characteristic or object.
Patent	'A patent is a contract (from the federal government) that grants the patent holder the right to exclude others from making, using, or selling the invention for a period of 20 years from the date of filing of the patent application' [1].

3. Historical aspects of intellectual property and patents: focusing on Europe and United States

The first surgical procedure was probably trepanation performed in ancient communities [2] and the first patents, '*litterae patentes*; an open letter' [3], are thought to have originated from Ancient Greece and Rome from which there are reports of protected food recipes [4]. The first recorded patent was in Florence in 1421. This was followed by a Venetian statute in 1474 and this heralded the start of modern European international patent law [5]. It is unclear when the first medical patent was issued.

In the United Kingdom, King Henry VI issued a '*letter patent*' in 1449 [6] and this was followed by formalisation of patent laws under the reign of Queen Anne. The 'letter patent' generated the term 'patent medicine' which referred to medicines with secret formulae. In 1852, the Patent Office was set up and renamed 'the UK Intellectual Property Office' (UKIPO), its current title in 2007 as described on the UKIPO website [Table 2, Link 1].

Patent law started in the United States in 1802 with the introduction of a Department of State official, '*Superintendent of Patents*' who dealt exclusively with patents. In 1836 this was revised to the '*Commissioner of Patents*'. The Patent Office moved from the Department of State via the Department of Interior in 1849 to the Department of Commerce in 1925 where it remains to this day. Renamed the 'Patent and Trademark Office' in 1975 it took its current name, the 'United States Patent and Trademark' Office (USPTO) in 2000. This history of American Patent law is derived from the USPTO webpage [Table 2, Link 2].

Historical medical patents of interest include the artificial limb patented in 1863 and the stethoscope probe in 1864 which are the first recorded patents that we retrieved. The hypodermic needle was not patented until 1949 [6]. Historical milestones are summarised in Table 3.

4. Patent administration and law

The administration of patents is subject to precise litigation and the application process is fastidious. Common principles exist globally but geographical differences introduce variation to the implementation processes. The main principles to consider in the management of patents and their

Table 2
Useful links and web-based references.

1	UK Intellectual Property office (UKIPO)	http://www.ipo.gov.uk
2	United States Patent and Trademark Office (USPTO)	http://www.uspto.gov/
3	NHS innovations for London	http://www.nhsinnovationslondon.com/
4	Confidentiality and confidential disclosure agreements (CDA)	http://www.ipo.gov.uk/cda.pdf
5	Patents application guide	http://www.ipo.gov.uk/p-apply.pdf
6	FY 2006 U.S. Licensing Survey Activity Survey Summary	http://www.autm.net/index.cfm
7	The Chartered Institute of Patent Attorneys' (CIPA)	http://www.cipa.org.uk
8	PACTT Technology Transfer	http://www.pactt.ch/
9	Imperial innovations	http://www.imperialinnovations.co.uk
10	Patents Act 1977 (as amended) UKIPO	http://www.ipo.gov.uk/patentsact1977.pdf
11	World Medical Association Statement on Medical Process Patents	www.wma.net/e/policy/m30.htm
12	EU Directive 98/44/EC	http://ec.europa.eu/internal_market/indprop/invent/index_en.htm
13	Patents: Commission adopts a second report on biotechnological inventions, covering gene patents and stem cells	http://europa.eu/rapid/pressReleasesAction.do?reference=IP/05/960&format=HTML&aged=0&language=EN&guiLanguage=en
14	World Intellectual Property Organisation	http://www.wipo.int/portal/index.html.en
	European Union	http://europa.eu/index_en.htm
	USPTO Fee Schedule	http://www.uspto.gov/main/howtofees.htm
	European Patent Office	http://www.epo.org/
	European Patent Office Search page	http://ep.espacenet.com/advancedSearch?locale=en_EP
	EU Report on Biotechnological Inventions	http://europa.eu/rapid/pressReleasesAction.do?reference=IP/05/960&format=HTML&aged=0&language=EN&guiLanguage=en

Table 3
Critical milestones of patent development.

Ancient Greece/Rome	Protected food recipes
1421	First recorded patent, Republic of Florence
1449	'letters patent', King Henry VI, England
1474	Venetian statute
1623	'Statute of monopolies', James I, England
1802	'Superintendent of Patents', United States
1836	'Commissioner of Patents', United States
1852	'Patent Office', United Kingdom
1975	Patent and Trademark Office, United States
2000	United States Patent and Trademark Office, United States
2007	UK Intellectual Property Office, United Kingdom

administration are evaluation, protection and licensing of intellectual property [7].

5. Evaluation

The first step of evaluation is to establish what the requirements are of an invention to qualify for a patent. The requirement is that the invention must be new, involve an inventive step and be capable of industrial application. Non-patentable inventions include discoveries, scientific theories, mathematical methods, schemes and the presentation of information or a computer program as described by 'NHS Innovations London' [Table 2, Link 3].

Once it has been established that the invention qualifies for a patent, the next step is to assess its patentability. This is influenced by two key factors; market factors (including the novelty) and patent issues. Evaluation of the patentability is best made by experts [8].

It is essential to establish that the idea is novel and has not already been invented and patented. This market analysis is ultimately formally performed by the Patent Office but it is good practise for the inventor to check first. An '*infringement clearance search*' (also referred to as a 'clearance search') determines the probability of infringing on other parties rights. This is quantified by 'risk' and can be a costly exercise when it happens. The procedure is to perform a search for any relevant publications which are the same or similar and the purpose is to identify any potential cross-over with other ideas be it graphical or literary. Generalised topic searches can be performed using popular search engines such as *Google* or *PubMed* and every Patent Office provides an on-line search facility for existing patents, which enables a rapid exclusion of potential infringement.

6. Protection/disclosure

An essential principle in the protection of intellectual property is discretion and this remains a key theme throughout the formal development and maintenance of the intellectual property. It is unanimously established that it is imperative from the earliest stage to establish confidentiality but there is a delicate balance between confidentiality and disclosure. Secrecy can be a confounding factor since, on the one hand lack of confidentiality and idea disclosure will compromise any future protection of intellectual property and on the other, the 'top secret' approach makes it impossible to collaborate with colleagues and/or experts so progress may be restricted and complicated.

Apart from being discrete, there are formal ways of establishing non-disclosure and this can verify evidence of 'date of creation'. Non-disclosure implementation varies geographically. The most basic first line is to keep a close record of the idea/s as a document with drawings. This should be signed by the inventor(s), countersigned by a witness and self-mailed but not opened on receipt. More formal non-disclosure arrangements are provided by confidentiality disclosure agreements (CDAs) also known as confidential agreements or 'non-disclosure agreements' (NDAs). These are recommended when discussing the idea with anyone other than registered lawyers or patent agents (since

discussion with these parties is considered safe and legally privileged). The formal agreements are prepared by lawyers or patent agents, are legally binding and record the terms under which secret information is exchanged. The UKIPO publishes an online PDF booklet for further advice in this area with an example of a CDA [Table 2, Link 4]. In the United States, confidential agreements are not essential when applying for a patent since the initial brief (preferably with drawings) can be forwarded to the USPTO and this becomes recognised as a formal 'disclosure document'. When this route is taken, the 'disclosure document' is filed for 2 years and may be used to retrospectively provide 'evidence of the date of conception of an invention'. Following this, it is destroyed. Though not recommended, if industrial collaboration is necessary prior to patent proceedings, a CDA should be used. It is CDAs that enable the existence and recognition of confidential information, which may be commercially or technically valuable and bought, sold or licensed. Such information is designated as 'know how' or 'trade secrets'.

For most medical inventions, the best available protection is established by the award of a patent although other protection routes exist. The process of patent application and administration is governed by very precise law and this may be complicated by significant geographical variation. For this reason, individual nations and grouped coalitions of nations have expressly dedicated government bodies. Common principles are adhered to although their exact implementation differs between regions. Early protection of an idea is unanimously essential and though the processes may be dissimilar, once secured, the main principles are patent application (or filing), granting of patents and finally patent maintenance. We attempt to highlight the main issues as below.

Completing the patent application varies in implementation between regions. The basic concept is to convey the concept or idea to the Patent Office using descriptive text and illustrative diagrams together with a fee. Justification of the novelty is included and the document should be written in such a way as to incorporate potential future applications of the idea. Emphasis should be made to specifically protect that part of the invention that best secures the owners and inventors monopoly of that intellectual area.

We will demonstrate some examples by comparing the application process in the United Kingdom and the United States (Fig. 1). In the United Kingdom (Fig. 1a) a 'patent specification' is prepared and submitted with Form 1 to the Intellectual Property Office. This submission which should include a description claims and abstract generates a receipt which defines the 'filing date'. In addition to the text, drawings should be incorporated which demonstrate how the invention works and how it is made. 'Claims' are sentences defining the invention and describing technical features. Form 9A is then submitted which instructs a 'search request'. After a 'preliminary examination' the application is published. A 'substantive examination' is requested by submitting Form 10. The Intellectual Property Office examines the application and if all the requirements of the Patents Act 1977 are met the patent is granted, published and a certificate is issued. Further detailed information is available from 'Patents: Application guide' published by the UKIPO [Table 2, Link 5].

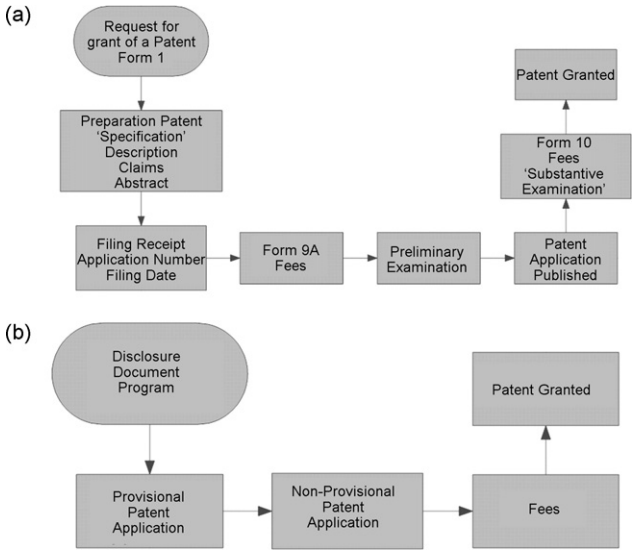

Fig. 1. (a) UK patent application process. (b) USA patent application process.

The process differs in the United States (Fig. 1b) and the following information is taken from the USPTO website [Table 2, Link 2]. The first step is to fill in a provisional patent application and this establishes the 'filing date' and permits the term 'patent pending' to be applied in connection with the invention The requirements are a filing fee and the inclusion of a cover letter but Claims, Oaths and Declarations are not required at this stage. A non-provisional application for a patent request is then submitted to the Director of the United States Patent and Trademark office. This requires a written document (written in English or with an English translation) which includes the specification (description and claims) and an oath or declaration. In addition a drawing should be included and the appropriate fee. As in the United Kingdom claims, the 'oath' or 'declaration' is the statement that declares that the inventor believes that he/she is the 'original and first inventor of the subject matter of the application'. Declaration forms are available from the USPTO by mail or Internet.

7. Licensing

Licensing describes the system through which the owner of intellectual property enables another person or company to use the intellectual property. Licenses can be exclusive, non-exclusive or sole and the licensor income is generated though a combination of fixed fees and royalties. Typical royalties are in the order of 2—5% of sales. It is also possible to sell the 'ownership' of an idea and this is termed an 'assignment'.

8. Multiple layers of protection

Patents provide a method of IP protection which may or may not be the optimal approach for a specific invention, especially considering the early financial commitment and complexities of geographical variation. In addition to

patents, different protective measures exist which afford diverse levels of security. Other tiers of protection are delivered by copyrights, database rights, registered and unregistered design rights and trade marks (NHS Innovations London website [Table 2, Link 3]).

Copyrights are automatic and exist automatically from the moment the work is completed. They protect the physical entity (for example written text, photographs, music) but not the idea. Database rights protect electronically stored information and design rights protect designs which may or may not be registered with the designs registry. The trade mark protects the 'sign or symbol that allows consumers to distinguish between different providers' (NHS Innovations London website [Table 2, Link 3]).

9. Patent development and sources of advice

Apart from fulfilling the legal requirements of patents, careful consideration must be made as to the overall strategy that will be recruited in their adoption. Examples of important early factors to consider include dilemmas of ownership, financial backing and recruitment of external specialists. The application process is complicated and it is unequivocally recommended that the lone inventor seeks professional assistance and advice.

In the first instance, it is essential and universally obligatory that health professionals check their local policy and contact their specific IP representatives since all trusts and institutions should have an IP policy which is usually compulsory. (Some trusts may permit the use of independent agents and independent individuals may secure a private patent attorney.)

'Technology transfer' recruits the assistance of specialists to develop inventions and links the inventors to the business world while legal offices facilitate the completion of IP protection. Formerly, such assistance was 'externally' recruited but there has been a shift to setting up internal technology transfer and legal offices within academic institutions and universities, especially in the United States. These offices have in themselves become a growing lucrative industry and in 2006, US academic centres received $45 billion dollars in R&D expenditures (The Association of University Technology Managers [Table 2, Link 6]).

In the United Kingdom, 'medically tailored' advice is available through the NHS which provides a web-based service for inventors — 'NHS Innovations for London' [Table 2, Link 3] and we strongly encourage readers to visit their website. This organisation provides a wealth of information on intellectual property and patents specifically for innovative health professionals. They recommend that the research and development department and/or intellectual property lead in the inventor's trust are initially contacted and they should invariably forward the process to the NHS innovations hub. There is the provision for their intellectual property managers to draft an application followed by the recruitment of a patent attorney to define the claims since this is felt to be the most cost-effective approach. For general (non-medical) advice, the UKIPO advises contacting a chartered patent attorney. Applicants are referred to a list of patent attorneys and this is available from the Chartered Institute of Patent Attorneys (CIPA). [Table 2, Link 7]. European institutions also provide technology transfer offices such as PACTT of the University of Lausanne (PACTT technology transfer website [Table 2, Link 8]) and Imperial Innovations [Table 2, Link 9]) and the European Union recently issued guidelines on the management of intellectual property in knowledge transfer activities [9]. Similarly, in the United States local institutions have installed well-developed departments which give advice in IP implementation and maintenance and fulfil 'technology transfer' responsibilities. Examples include, the Mayo clinic [8] and Harvard University (The Association of University Technology Managers [Table 2, Link 6]) where there is provision of 'in house' expertise, patent attorneys and 'collaborative brainstorming'.

Internationally, invention promotion companies also exist, offering expert services to people wishing to take out patents. The inventor can work with such companies but it is important to get independent legal and financial advice. When contacting such companies it is essential to maintain a non-disclosure policy until such a time that a confidentiality agreement is agreed and trust is established. Start-up companies require approximately $10—20 million dollars to successfully bring devices from conception to the market-place and this is following several rounds of financing.

10. Influence of geographical variation on patents

Patent implementation and law varies geographically and inventors need to consider both local and remote IP protection options. Patents are normally applied for in the country from which the idea originates; however it is important to establish more geographically comprehensive protection. If this is not done, it is hard to defend manufacturing rights should another party wish to assemble the product elsewhere. (This is an area where multiple layers of protection may be especially helpful.)

A facility which helps to address the problem of geographical cover is the existence of patent treaties. These legally coalesce geographical zones to enable more regionally comprehensive applications. It is possible to submit a singular standardised application which enters a centralised filing procedure covering multiple nations. The main treaties are the patent co-operation treaty (PCT) and the Paris Convention for the Protection of Industrial Property. The European patent convention or PCT, conceived in 1970 is formed by the United Kingdom and 137 other countries including the United Sates. The Paris Convention for the Protection of Industrial Property which is adhered to by 168 countries, entitles the citizens of its member states to equal rights in patent and trade mark matters. It also enables for right of priority which permits effective retrospective filing throughout the treaty members to the date of the first application (USPTO website [Table 2, Link 2]. International applications can be made via patent conglomerates such as the European Patent Office (EPO) or the International Bureau of the World Intellectual Property Office (WIPO) in Geneva which utilise these treaties.

When trying to achieve increased geographical cover, the common first step is to apply to the national office of the

country of origin since this sets the 'priority date' (USPTO and NHS Innovations London websites [Table 2, Links 2 and 3]).

For the United Kingdom, a PCT application should be submitted within 12 months of the UKIPO filing and this can be done via EPO or WIPO. Akin to the United Kingdom, to achieve IP protection in another country, the American inventor needs to apply directly to that country or via a regional Patent Office since United States patents only cover the United States (USPTO and NHS Innovations London websites [Table 2, Links 2 and 3]).

It is essential to get the time schedule right since patents will not be awarded if there is publication of the invention prior to the application date (unless the application is through an international treaty). Furthermore, there is stipulation that the invention is manufactured in the country from which IP protection extension is requested and failure to do so may nullify the patent if it has been awarded. In addition, if a non-US patent is applied for a US invention before or within 6 months of a US patent, a license must be granted from the director of the USPTO (USPTO website [Table 2, Link 2]).

For multi-national applications, the searches are carried out by the International Search Authority and the International Bureau publishes the patent application. After publication, an international preliminary examination is requested. It is important that the 'national phase' is entered in each country prior to the deadline which is usually 31 months after the priority date (USPTO and NHS Innovations London websites [Table 2, Links 2 and 3]). To achieve worldwide cover is not economically feasible since there are around 200 states and the cost would be astronomical. Usually, 20—30 states are covered prioritising them economically and marketwise. This generates a cost of at least $200,000.

The WIPO Patent report of 2007 has demonstrated very high growth rates in the use of the patent system in north east Asian countries especially in the Republic of Korea and China. The distribution of worldwide patents is varied with Japan and the United States receiving the greatest number of patent applications. Source: the WIPO Report, 2007 edition.

11. Owner versus inventor?

It is important to clarify who is the owner and who is the inventor since these roles have different implications with important variable financial outcomes. The inventor is the person who has the idea whereas the owner is the person or body that control the property. The owner holds the intellectual property rights but the inventor is only nominally accredited with the invention and essentially otherwise powerless over its administration. In the application process for patents there is scope to separate these roles and an application can have more than one inventor.

In the United Kingdom, the National Health Service (NHS) trusts own all intellectual property generated by their employees in the course of their employment as described in the Patent Act of 1977 which is available on line via the UKIPO [Table 2, Link 10]. The 'inventor' is recognised in that capacity but the trust takes ownership. In this respect, trusts are encouraged to develop a revenue sharing scheme.

An example of a revenue sharing scheme is that employed by CHUV, the University Hospital of Lausanne which after patent costs keeps 10% for PACTT and distributes 30% to the inventor, 30% to the unit and 30% to the institution (PACTT Technology Transfer [Table 2, Link 8]).

In Spain, 'Superior de Investigaciones Científicas' (CSIC), the Spanish National Research Council, owns research patents but new legislation permits an equal revenue sharing scheme between inventors, the council and the institution or company to which the inventor belongs [10].

In the United States, the situation is now different. As in the United Kingdom, the federal government retained patent ownership until the owner inventor relationship in academic universities and institutions was radically re-addressed through the introduction of the Bayh-Dole act in 1980. Through stating that 'the control of intellectual property generated by federal funding is granted to the universities and other nonprofit organisations which used the funding for the research that led to the discovery' [11] the ownership is retained by the recipients of federal funding and as in the UK, most universities/institutions specify that a portion of the rewards must be returned to the school. [12] The Bayh-Dole act has promoted the development of inventions and their commercialisation. Specific IP procedures are region/institution/affiliation exclusive and there are therefore differing agreements.

12. Entering the market-place

Apart from securing IP legal protection, when bringing inventions to the market-place, there are several important factors which must be considered. These include the relationship between patent development, commercialisation and industrial collaboration, models of technological innovation, recruitment of financial assistance, adherence to compulsory regulatory routes and the timing of IP protection. These topics are broad and complex, rendering them beyond the remit of this paper.

13. Costs and fees

Patent applications are costly and the amounts vary internationally. Initially there is a filing and application fee followed by ongoing maintenance fees which are substantial. The greater the domain covered, the greater the costs. We illustrate using the United Kingdom and United States fee schedules.

In the United Kingdom filing forms with the UKIPO requires fees. Form 9A costs ~$225 US dollars (£130) which includes ~$175 US dollars (£100) for the search and ~$50 US dollars (£30) for the application fee. Form 10 costs a further $120 US dollars (£70) for the substantive examination. In addition patent attorney fees are charged quantitatively on a time basis. The overall cost is dependant on the complexity of the patent. An average complete UK based patent costs $5240—8730 US Dollars (£3000—5000) (NHS Innovations London website [Table 2, Link 3]). The cost of applying for and securing a United States patent is >$20,000. The United States Fees Schedule is complicated and difficult to summarise. It may be downloaded from the USPTO

[Table 2, Link 2]. If worldwide patents are secured the cost can be at least 10 times greater [8].

14. Duration and timeline

A patent usually takes 2–3 years to grant. The procedure can be fast-tracked on request and maximally take four and a half years. The patent lasts 20 years from the time of filing.

15. Ethical considerations for healthcare patents

Introduction of intellectual property into the healthcare world and union with commerce inevitably brings about ethical anxiety. Regardless of the area being deliberated, when applying for healthcare patents the incorporation of ethical consideration is of paramount importance. It is necessary to contemplate healthcare patents in well defined groups (for example; devices, procedures and biotechnology) since differing medical areas oblige distinct ethical principles.

The balance between the advantages and disadvantages of medical patents must be carefully considered since difficult dilemmas such as conflicts of interest, concern of inhibition of dissemination of knowledge and the conflict of personal gain versus patient benefit may be unconstructive to patient management and this remains the main concern.

Medical device patents are considered permissible and ethical on an international level. 'Medical and Surgical Procedure Patents' or 'Medical Procedure Patents' are permitted in the United States which is of special interest to surgeons, whereas they are not in Europe and the United Kingdom. Such patents are inclusive of surgical technique. The notion was challenged in 1996 in the case of *Pallin v Singer*, where Dr Pallin failed to enforce patent claims on a specific incision used in cataract surgery [13,14]. 'Medical Procedure Patents' remain permissible despite non-favourable arguments issued by the Council on Ethical and Judicial Affairs (CEJA) of the American Medical Association [15,16]. In fact, United States Medical process patents issued since 1996 have not been enforceable against those infringing upon them through performing a medical or surgical procedure and this renders them practically meaningless. The World Medical Association position on Medical Procedure Patents issued in 1999 [Table 2, Link 11] expresses concern that such patents may limit the availability of new procedures to patients and considers such patents unethical.

This is of interest in the context of surgical specialties since in principle it is possible to patent a technique, especially if it includes the use of a medical device which is a common scenario in cardiovascular surgery. It is noted that this information has either not diffused into practise or is not actioned for legitimate 'other' reasons since to our knowledge there have been no attempts to intellectually protect traditional cardiovascular surgical techniques such as the implantation of valves.

16. New challenges and frontiers

It has been established that it is possible to patent devices and the process is tried and tested, but ongoing scientific development in novel areas has obliged the introduction of new IP frontiers. A key growth area is that of biotechnology which presents an entirely different IP challenge with consequent complex litigation. This is relevant since stem cell technology has entered the thoracic and cardiovascular experimental and clinical forum. For example, the use of transplanted tissue engineered cell sheets to seal lung air leaks and new areas of cardiac surgical research which are demonstrating that introduction of stem cells by different routes results in observed cardioprotection [17,18].

Patents have been successfully applied for in this domain. Bergman et al. state that there has been a recent increase in the number of patent filings in stem cells and they have shown that the European Patent Office has received 560 publications and granted 421 patents covering 'uses, methods, or compositions involving human or animal stem cells' and the USPTO has received 3711 applications and granted 1724 patents [19].

Biotechnological IP management is managed differently in Europe and the United States. In Europe, the litigation is directed by the European Union. To address biotechnological inventions (stem cells and regenerative medicine), the European Commission issued Directive 98/44/EC [Table 2, Link 12]. This was further revised with a second report in 2005 which is the last update we could find on searching the European Commission Internet site [Table 2, Link 13]. The report essentially highlighted the difference between totipotent stem cells and pluripotent embryonic cells. The former were deemed unequivocally un-patentable since they have the capability of developing into a human being. The latter are still under review. However, in the United States, the picture is very different and controversial, dating back to patents awarded to the Wisconsin Alumni Research Foundation (WARF) in the 1990s which claim all primate and human embryonic stem cell lines [19].

17. Current trends and examples of patents in thoracic and cardiovascular surgery

Thoracic and cardiovascular surgery are key examples of surgical specialties that require a vast array of equipment. As surgical possibilities develop so must technology follow and as a result, there exists a wealth of thoracic and cardiovascular surgical devices. This remains a rapidly growing area. A single example is the relatively recent introduction of surgical ablation for atrial fibrillation into cardiac surgical practice which has brought with it a wide variety of new devices to enable implementation of this novel surgical technology.

We performed a search of international patents using key cardiothoracic and cardiovascular terms and demonstrate these findings in Fig. 2a. Key terms searched for were: cardiac surgery; heart surgery; coronary surgery; thoracic surgery; lung surgery, chest surgery; cardiovascular surgery, cardiothoracic surgery, heart valve, heart cannula, heart retractor and coronary anastomosis via the UKIPO, World Intellectual Property Organisation [Table 2, Link 14] and USPTO. The search was conducted between 21st May and 6th October 2008 and demonstrates the key area of heart valve technology. Our search strategy is exemplified by the term

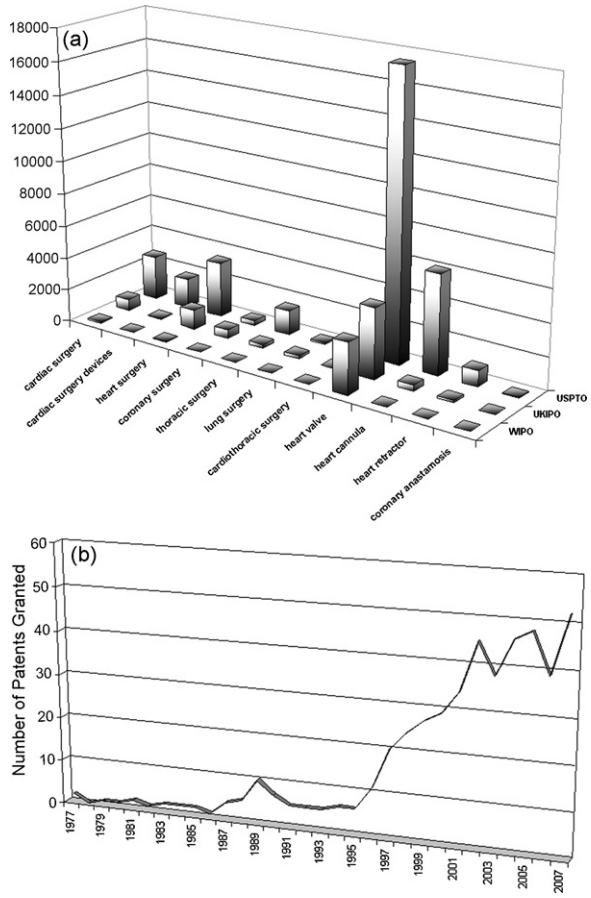

Fig. 2. (a) Worldwide patent search for cardiothoracic terms. WIPO: World Intellectual Property Organisation; UKIPO: United Kingdom Intellectual Property Office; USPTO: United States Patent and Trademark Office. (b) Number of worldwide patents for 'cardiac AND surgery' searched for via British Intellectual Property Office from 1977 to 2007.

'cardiac surgery'. The WIPO search was entered as 'cardiac_surgery' and 'all fields' were searched. The UKIPO search was constructed by searching for 'cardiac and surgery' limited to 'words in the title or abstract' and for the 'worldwide database'. The USPTO search term was 'cardiac surgery' for 'all fields' from '1976 to present'. As seen in the figure, searching the international database for the same terms revealed a significant discrepancy in numbers between the results of searches via the different nationality based search engines. Furthermore, we identified that searching for cardiothoracic related patents can be unreliable. This is demonstrated by the search term 'cardiac surgery device' which revealed only 1 patent via WIPO, 73 via the UKIPO and none via USPTO. This clearly underestimates the data and reinforces the notion that extreme caution must be taken when searching for patents.

In addition, we searched the international patent database for the terms 'cardiac AND surgery' via the UKIPO search function [Table 2, Link 1]. This demonstrates a dramatic increase in the number of cardiothoracic patents in the last 10 years (Fig. 2b).

This search demonstrated the wide scope of thoracic and cardiovascular patents when searching for related patents in general terms but even within the specialty, examples shown in Table 4 demonstrate the broad potential for devices.

Table 4
Diversity of cardiothoracic equipment and devices.

General	Scalpels	Skin, artery
	Diathermy	Monopolar, bipolar
	Saw	Sternal saw
	Access	Retractors
		Ports
		Minimally invasive
Procedural	CABG	Anastomotic devices
		Aortic and venous cannulae
		OPCAB devices
		Robotic equipment
	Valves	Mechanical, bioprosthetic
		Rings (annuloplasty bands)
		Robotic equipment
	Ablation	Ablation devices
	Assist devices	
Closure	Bone closure	Wires, sternal clips
	Skin closure	suture, staples, glues
Aftercare	Drains	
	Dressings	
Miscellaneous	CPB	Perfusion pumps
	Perioperative imaging	Ultrasound, probes, TOE
	Glues and sealants	
	Monitors	

18. Discussion

It is established that it is important to remain contemporary in medical and surgical practise such that the best available interventions and treatments are offered and available. We have discussed how the adoption of technology requires the practise and application of IP. Once an idea is created, there is a massive amount of territory to be covered prior to the physical development of a real device that can be safely introduced into the market-place.

The first hurdle is that of confidentiality. It is prudent to maintain this at all times and as discussed there are formal and informal ways of enforcing this. Following the successful institution of non-disclosure, further challenges and their interaction are encountered that can be thought of as 'internal' and 'external' factors. 'Internal factors' relate to the individual with the idea. In developing innovation and acquiring intellectual property the key for the individual is to demonstrate knowledge and awareness of the processes and systems used to protect IP. Utilisation and practise of innovative and leadership skills also contribute significantly. 'External' factors include all non-self entities. This includes peers and colleagues, the trust or hospital, the university or academic institution, legal and technology transfer offices, ethical institutions and the Patent Offices. Liaison with these groups is inevitable, essential and introduces an interesting dichotomy. The key principle is to limit exposure and sharing of knowledge to only 'essential' parties and formalise as much as possible the confidentiality agreements.

Combining healthcare and the commercial world through the use of IP inevitably introduces delicate ethical issues. The main concern is to protect any potential threat of compromised patient care. Potential challenging influences

include incorporation of business plans and the temptation of personal gain. A balance between protection issues and patient care must be found in favour of good medical practise such that patient care never suffers as a result of commercialisation and business development.

To facilitate these potential pitfalls, the relation between the inventors and the commercial world via academic institutions and trusts are well defined and often managed by specific departments such as technology transfer offices and university legal offices.

Taking thoracic and cardiovascular surgery as examples, these are surgical specialties undergoing significant change. For example, in cardiac surgery, the bulk of cases were historically coronary revascularisations, but routine practise has grown to encompass several other cardiothoracic operations. When there is surgical evolution, technological development must progress equally fast to support it. It is therefore a natural consequence that new ideas and devices are continuously being introduced. These ideas require intellectual property protection and patent management. An understanding of patents and their ramifications should facilitate the modern day thoracic and cardiovascular surgeon in their practice and encourage ongoing surgical development.

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Appendix A. List of abbreviations

CDA	Confidentiality disclosure agreement
CSIC	Superior de Investigaciones Científicas
CEJA	The Council on Ethical and Judicial Affairs*
CIPA	The Chartered Institute of Patent Attorneys
EC	European Commission
EPO	European Patent Office
EU	European Union
IP	Intellectual property
NDA	Non-disclosure agreement
NHS	National Health Service
UKIPO	United Kingdom Intellectual Property Office
USPTO	United States Patent and Trade Office
WIPO	World Intellectual Property Organisation
WMA	World Medical Association

* Of the American Medical Association.