A4M™
Agents For Medics

A4M: All About Ideas Information Sheet

Having that great idea is just the start of the process to making that idea a reality.
Below you will find information about the processes involved in bringing an idea to market. Agents For Medics has been created to help to take that idea through that process and improve the chances of your success.

An idea is often referred to as: Intellectual property (IP)

Defining Intellectual Property:
The Intellectual Property Owners (IPO) Association defines intellectual property as:
"intangible creations of the human intellect that are protected by law."
Note: However, these laws can vary by country.

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Part 1: Protecting your ideas

Above anything else, you must protect your ideas. If not, then they have little commercial value. You need to think about protecting your ideas in terms of: Allowing you to put your idea on the market, not (as is commonly thought) stopping others copying your idea.

Disclosure Agreements:
Before anything else – no matter who it is – you should put in place a Disclosure / Non Disclosure agreement. This is even more valid if your idea is not patented. A4M – Insists that all clients have NDA's in place before looking at your ideas.
Even if you have a patent – you may have some technical knowledge, process or marketing idea that is not covered in your patent. All this knowledge has value.

Patents:
This is a vital step in protecting your ideas and making them commercially viable. Rules and ways of submitting patents vary greatly from region to region. For general information on patents, you should visit the links on our site to "US Government Patent office" or "European Patent Office"

What is a Patent?:
A patent refers to the rights to an invention, granted by a governing body. In principal, they exclude others from using, making, selling, offering for sale, or importing an invention without the permission of the inventor.
Note: Patents do not automatically grant the patent holder the right to offer for sale, sell, make, use, or import an invention. Securing these rights may involve additional steps.

Filing a Provisional:
This is a way for you to start the process of protecting your idea. It allows for a provisional filing of the idea while you prepare you patent submission. This is relatively cheap.

You must pay for patents:
This is a vital investment if you consider commercialising your idea. If it's not worth the cost of a patent – then the idea isn't worth anything.

What does it cost?:
The first thing you need to pay for is to search for any existing patents on your idea – or something very similar. This up front investment can save you a lot of expenses and wasted time in the future. If it already exists then

you may not be able to patent it. If you can't patent it, then it has limited commercial value.

Patent or Prior Art Search:
The cost of searching for this information can vary greatly, depending on the nature of the search, who does it and where they look. This phase cannot guarantee that you will be granted a successful patent – but it will greatly improve the chances.

Once you feel confident you are "Clear" of other patents you then need to apply for your patent.

Applying for a patent:
Again, the costs of applying for patents vary greatly. It is dependent on what you are patenting and where you are patenting. Application fees schedules for the US can be found at the USPTO website (www.uspto.gov). Or for Europe, at the European patent office website.

It should be noted that once you have applied for and been granted the patent, you will need to continue to pay to maintain that patent. These are called "**Maintenance Fees**" and you are required to pay at certain times – failure to pay in a timely manner can risk the expiration of the patent.

The preparation and filing of patents is a fine art, ensuring that the information given is correct, and written in a legal manner which will fully protect your ideas. It is not advisable to try this alone. You should invest in a good patent agent or patent lawyer to perform this complex task.

What about covering your idea internationally?:
"More than 140 countries participate in the Paris Convention for the Protection of Industrial Property, which guarantees that citizens of other nations are protected by the same patent rights as the same laws as their own country."
By filing this type of international application, you are covered in 90% of the countries that signed this cooperative agreement.

But patent laws do vary by country. Local laws can dictate where the initial filing must occur and other complex rules. A good patent lawyer will again find out the different rules and regulations for you.

Note: International Application:
If a patent is filed before or within 12 months of filing a U.S. application, the U.S. government requires that inventors obtain a license from the

Commissioner of Patents and Trademarks in order to file an international patent application.

Details on the patent process:
Before anything you should do a good deal of research into the field where you wish to patent your idea. Just having the patent is not a guarantee of success. A professional marketer or research company will help you to assess if you idea has a chance of commercial success.

A. Filing a patent
As the inventor, you begin the application process by filing for a patent. However, if others assisted in inventing, you will need to file a joint application. Or, if you have assigned your rights to another person or even a company, the patent will eventually be granted to the assignee's name. But ultimately you will be listed as the inventor.

Components of a patent application:
Specification — This is a written description of the invention. It should include the manner and process of making it. Importantly it must state its claims, and must state what differentiates it from other patented inventions.

Diagrams (Optional) — This is a technical aspect that has strict guidelines which must be followed. Diagrams must stick to the guidelines e.g. type of paper, size of diagram, labelling, margins, etc.
Again, the US Patent office issues such guidelines for US application.

Oath — This simply is a declaration that the applicant for the patent believes they are the first inventor of this idea.

Fees — See section above on what it costs to file a patent.

B. Process of Examination
Once you have filed for your patent, it will be subject to the process of examination. This process is performed by experts in the field of patents (most usually in the field in question. The examiner will send the application through a patent search for similar U.S. and international patents. In determining if a patent can be granted they will answer these questions:
Is it novel?
Is it not obvious?
Is it useful?

C. Office Action – Notification
The examiners decision (acceptance or rejection) will be given in a written communication. It may be some years until this decision is given. Until that point you will advance with your invention with a certain degree of risk.

D. Applicant Action - Reply
In the event that the examiner / patent office rejects claims made in the patent application, the applicant must submit a formal reply addressing each and every objection made by the Office. In general there are six months to submit a reply, but this time period can be shortened to as little as 30 days.

E. Final Rejection
If the patent office determines that the reply does not overcome their objections, a formal final rejection is sent.
Note: This "final rejection" does not mean that a patent cannot still be obtained.

F. Appeal Process
In the event of being sent a final rejection from the patent office, the applicant has the opportunity to file an appeal with the Board of Patent Appeals and Interferences at the USPTO. The appeal can take the form of an oral hearing, for a certain fee. Also the applicant has the option (if they chose) to file a continuation application.
If these appeals are NOT successful, there is a last alternative. A final appeal can be made with the Court of Appeals. Or an alternative, but costly route, is to file a civil law suit.

Note: The process described above is based upon a US patent application. Other countries may have variations upon this process. Advice should be taken from a patent lawyer or patent agent.

Part 2: Putting Value to your idea

Simply having an idea, and having a patent on that idea is not enough to make money from that idea. The idea itself must have a value:

What's Your Idea Worth™

This is the mantra of Agents For Medics. And this is an important question you need to answer. So how do you value ideas?
No matter if you are deciding to make the invention yourself, licence the idea or sell the idea – it must have some value.
Whoever ultimately owns the idea must be able to make money from it – money that will at minimum repay the investments made to get that idea.
Normally a company will only consider an idea if they feel confident it can not only pay for itself but contribute significant profits in the future.

Companies spend vast amounts of resources to assess any new ideas. They must determine – how much they will need to spend to realize the idea and potentially how much (and for what price) they can then sell that idea / product.
This is a very complex process that often requires market research, legal advice, financial experts and marketing experts.

To value your idea you will need to consider the following factors:

Legal and Safety aspects
Are there any legal restrictions regarding your idea?
Will this imply costly regulatory hurdles? (Attaining CE mark – FDA)

This may in turn determine what clinical trials will need to be performed to address these issues. (Clinical trials may imply millions of dollars of investment.)

Business Risks
What are the potential business risks you will encounter?.

Functional Feasibility: Will your invention actually do what it is intended? (how will you prove this?)

Production Feasibility: What equipment and resources are required to manufacture and market your invention? (Who will make it?)

What stage of development are you at? (Is the base technology new, stable, and readily available?)

How much investment will need to be made up front? (will it cost too much to develop?)

How long will it take to make back the money?

The idea is great – but will it eventually make profit? (Is it just so expensive to develop, make and distribute that the selling price would be too high to ever sell)

Do you need extensive Marketing Research? (What more needs to be known about the device, market and competition?)

How much more Research and Development will be needed. (How much time and how much money will it take?)

How much is the device needed? (If I make it , will someone really be willing to buy it?)

What's the Potential Market (Can I sell 1 or 1 million? How much can I charge for it)

How much will we realistically sell? (Are there alternatives, competition, reimbursement restrictions? Will something in the market stop me selling as much as I think?)

Will it sell in the market place?

Is it compatible with normal medical protocols? (Will we need to create a new market?)

Will we need product / procedure education? (How much will we need to do, how much will it cost? How fast can we do it?)

Is there really an unmet need? (Or is the invention just a slight improvement on an existing product)

Will my product need other existing products to work? (Do I have the right for my product to be used with other products? Will it work?)

What will the competition be? (How will existing and future products impact the value of my product? Do I need to make financial models around this?)

Does the product look different from other products? Does it function differently? Will it fall to pieces? Is it as well made as existing products?
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How much can I charge for the product? (What is the market willing to pay and CAN they pay? Does reimbursement exist or will we need to change the entire reimbursement system?)

Will competitors out price this idea?

How well will the patent protect the product? (is it easy for companies to engineer around the patent? How unique is the idea?)

By answering these questions you will determine two things:

A) How feasible it is that the product will be a success.
B) How much value does the product have.

Here is a simple way of looking at the value:
Total value of product sold – Total cost of bringing the product to market = Value of the product.

Agents For Medics has a team of professionals to answer these questions and determine the potential value of your idea.

Part 3: Selling the idea

Once you've protected your idea and then estimated the value of that idea you will be faced with several important decisions on selling the idea.

A) Will I make it and sell it myself
B) Will I licence the idea to someone else or another company
C) Will I outright sell the idea to another person or company

All of the above have their own advantages and disadvantages. These must be weighed up with great consideration.

A) Selling it myself

This is probably the hardest way to deal with a medical device idea. It will involve dealing with many 3rd party specialists to ensure that design development, regulatory, manufacturing etc are all performed correctly and legally.

Finally you will then need to find distribution, sales and payment channels for your product. This can be a potential mine field and again will require professional support.

The advantage to going down this route is that you will retain a larger proportion of profits. This must be balanced against the increased costs and risks of trying to realize the product as a small company. On average 5 out of 100 medical device start up companies reach success.

If you decide against developing your idea alone, you have two options—licensing or assigning. Licensing is in essence leasing an idea. Assigning is the sale of a patented idea.

B) Licensing your Idea

Licensing an invention means you give a company "the rights" to produce and sell your invention. Usually this licence is for an agreed period of time. Compensation is agreed for this licence.

What's good about licences?

Sometimes licensing can be better than outright selling your idea. This is because some companies prefer to engage in licensing deals with inventors. For them, licensing reduces some of the risk and uncertainty

before the device is proven in the market place. It allows them to “test” the product before purchasing the idea.

It also allows the company to “delay” paying for the idea until the idea is generating revenue. This eliminates some of the major cash risk associated with bringing a product to market.

C) Selling your idea
To sell or assign your idea to a company, both parties must agree to the value of your idea. That is the possible future value of that idea. (see the section on valuing and idea for more details). Normally, when selling your idea you get a cash sum up front and / or payments at set milestones (agreed time points) such as product launch.

What’s good about selling your idea?
Simply put – Cash! You stand to make instant money and gain an instant return. But often companies will want to licence.

How do I licence / sell the idea to a company?

This is potentially the most difficult part, and often least successful part of the entire idea development process.
To understand why this is, you must consider the position of a company.

Most large companies are inundated with new product ideas – from individual inventors, from clinicians, from employees and from medical device companies.
The ideas arrive in many forms and in many stages and often they are exactly like products the company already has in development.

Product ideas can come as a drawing on a napkin, a scrap of paper, a professional drawing, a prototype or any configuration. This can be an overwhelming (and legally dangerous) position for a company. The last thing they want is a multimillion dollar research and development project derailed because an idea from an individual is submitted and the correct non- disclosure documents were not in place.

Often ideas come to the wrong company at the wrong time. They are just not in a phase where that idea can be considered.

This often leads to a policy of rejection of many ideas. - (often not for the right reasons). Many inventors wait for up to a year for a response, only to be told “No thanks.” This can be demoralizing and costly.

An alternative is to get your lawyer or patent agent to act on your behalf – but they are often not specialized in the field of medical devices and they do not have a deep understanding how to present to these complex organizations.

To consider selling to a company you need to understand several key things:

A) Is this the right company for this product
B) Is this company in the right phase to consider the product
C) Who is the right person to go to – marketing, sales, R&D. L&A – the president of the company? – Who will thoroughly examine this idea.
D) What stage should the product be in
E) Do I need to have the product patented
F) What market assessment data do they require
G) In what format do they accept idea submissions
H) Do you mail, email, send the idea, present the idea
I) What should I expect as a response
J) How long should I wait for a response
K) How often should I call back
L) What % should I ask for
M) How much should I ask for
N) When should I get paid
O) What if they don’t eventually develop the product

By answering these key questions, you will be better prepared to approach a company. It is better as an individual to present to one company at a time. Select your preferred company first.

Note: Any final negotiation should be performed by a professional. Contract negotiations are lengthy and complex and often involve many trigger points for payment.

Part 4: Funding your idea

It is important to understand from the beginning that turning your idea into reality will take funding. The extent of the funding will be determined by:

The nature of the idea
How far you wish to develop it
How many third parties will be required to develop the idea
How many countries you wish to protect the idea in
If you wish to bring the product to market or not

The path that you chose will determine how much money and hence the source of the money required to fund the idea.

Funding it yourself

Many ideas can be self funded to bring them to an adequate state of development. The idea can be brought to a state of prototype for reasonable amounts of money.

Raising Venture Capital

An alternative is to look for investors. This may be easier if another party contributed to the idea or invention.
There are also dedicated Venture capital firms that will offer funding at a price. They may provide initial capital to develop your idea for a financial stake in the product's success.

Note: Again, there are major risks to attempting to bring a product to market. Few inventions make it through this tortuous path. Any investments in your ideas must be considered as high risk. Take professional advise on these investments.

Part 5: Risk versus Reward

It is possible for any individual to take a product from idea to market – but it will require large sums of investment in both time and money. Many individuals create their own start up companies – but few succeed.

In considering how best to deal with your idea, you should consider the large potential rewards against how much time, effort and capital you are willing (or are able) to invest.

Part 6: How can Agents For Medics Help

A4M has a deep understanding of the processes involved in making your ideas a reality. Our professional team has a vast experience in agency negotiation, medical device development and medical device marketing.

Our service is designed to increase the chance of product success, reduce the amount of capital you will need to invest and handle all of the complex tasks for getting a product ready for sale.

Through our in house production facility – we can handle all issues of protecting your idea, developing your idea and preparing your idea for licensing / sale or setting up of a start up company.

The best ideas will also be subject to funding opportunities from the A4M fund.

In short: We look after the complicated issues, so you can continue your medical practice, yet still see your idea realized.

Visit us at : www.agentsformedics.com
To see how we can help to realize your idea.

Glossary of terms:

Assign
Used with intellectual property to denote the ownership of an invention. To assign is to sell the ownership of a patent or other intellectual property rights.

Capital
The financial resources and property that a company owns or requires to do business.

Conception
Conception often refers to the mental act of generating the idea of the invention. Should be documented, witnessed, and permanently bound in a page-numbered laboratory notebook or notarized records as evidence of conception of an invention. Clear and complete explanation of the manner and process of making and using the invention in sufficient detail to enable a person having ordinary knowledge in the field of the invention to make and use the invention.

Confidential disclosure agreements (CDAs) (NDAs)
See also non disclosure agreement. An agreement between parties whereby at least one of the parties agrees to keep something confidential, such as the invention. CDAs are sometimes referred to as nondisclosure agreements.

Copyright
A right granted by the registrar of copyrights in a work of authorship enabling an inventor to keep others from plagiarizing his or her literary, dramatic, musical, or artistic works.

Ergonomics
An applied science concerned with designing and arranging things people use so that the people and things interact most efficiently and safely—called also human engineering or human factors.

Funding (Financing)
Providing money or resources to support the development of an invention.

Gold Standard
A term used to refer to a product or procedure widely considered the best available to date (and most widely used)

Innovation
The introduction of a new idea, method, or device; novelty.

Intellectual property (IP)
The legal ownership of patents, trademarks, service marks, copyrights, know - how, trade secrets, and the like.

Invention
A new article, mechanism, or compound that has been created through investigation and/or experimentation. An invention is new, useful, and nonobvious from what workers skilled in that art might expect.

Joint application
An application in which the invention presented is that of two or more persons.

License
A contractual relationship between two or more parties that conveys rights to intellectual property.

Licensee
The person or company to whom intellectual property rights have been conveyed.

Market research
Research into the size, location, and makeup of a product market.

Marketability
The degree to which your product or service is perceived to be of value and will sell to relevant professionals and related organizations.

Narrow claim
The scope of a patient claim may be said to be narrow when it covers a specific implementation of the invention; a claim that is too narrow fails to cover significant embodiments of the inventions that are included in the specification.

Need (unmet need)
An expression of a product, process or procedure that would make the job of the clinician easier, faster, or safer. A need does not describe how the product, process, or procedure would be made. A need is not an invention. A need may also be referred to as an unmet need.

Non disclosure agreement (NDA)
Often used to describe a confidentiality agreement. Instead of claiming confidentiality, a nondisclosure agreement stipulates that the party will not disclose information. See also confidential disclosure agreement or CDA.

Not obvious
An invention is not-obvious if one with ordinary skill in the relevant technical art, and has access to all prior art available at the time of the invention was made, would not have known of, made, or used the invention.

Novel
New. One of the three main conditions for patentability; a claimed invention is considered new or novel if it is not anticipated by prior art. Many patent offices define novelty as not being revealed or publicly available anywhere in the world before the priority date.

Patent
The rights to an invention, granted by the government, to exclude others from making, using, selling, offering for sale, or importing an invention without the patent owner's permission.

Patent agent
A professional registered with the USPTO to file and prosecute patent applications; they cannot give legal advice or litigate; they can render patentability opinions.

Patent attorney
An attorney who has been certified as a patent agent; a patent attorney may represent a client in civil, business, and other interactions, in addition to those between an inventor and the USPTO.

Patent Cooperation Treaty (PCT)
Many countries are members of the PCT, which was created in 1978 to allow inventors to file one international patent application in one member country while designating the application for one or more member countries.

Patentability
An invention must meet the three basic requirements of utility, novelty, and not obviousness; the inventor must be the original inventor, and must file the application within the required statutory limits.

Potential market
Usually refers to the total number of procedures performed annually in which a device or its substitutes can be used.

Prior art
Other inventions or ideas in existence that are similar to, or offer features related to, a specific invention.

Priority date
The formal date on which one makes the first patent application. For those filing in the U.S., this is the beginning of a grace period for filing foreign patent applications. Not to be confused with the conception date, which gives preference over another inventor in the event of interference.

Product life cycle
The length of time between when a product is introduced to the market and when sales drop off to negligible.

Prototype
A first-of-a-kind working model or likeness of an invention that emulates at least some of what it is intended to do.

Return on investment (ROI)
The amount of money one receives relative to how much money was invested; can also refer to the payback period, or the time it takes for the return to surpass the investment.

Right to use
The ability to make, use or sell a product unencumbered by a second parties unlicensed intellectual property.

Risk analysis
A process in which the clinical, technical, and commercial aspects of a product or concept are analyzed in order to identify, assess, and prioritize the risks to its success.

Royalty (Royalty Payment)
A payment received based on a commission from sales of an invention or in some other acceptable form of remuneration.

Suggestion
Can be described as wants, needs, feedback, or even a great idea, although they lack the essential elements of an invention; Novel (new), useful, not obvious.

Thought leaders – (Key opinion leaders)
An individual on the cutting edge of their profession; see innovation.

Trade secrets
Intellectual property of value that is not readily known by others. Trade secrets have a specific set of laws governing them.

Usability
The state of being convenient and practicable for use.

Useful
As defined by the USPTO in reference to what can be patented: the subject matter has a useful purpose and also includes operativeness, that is, a machine that will not operate to perform the intended purpose would not be called useful, and therefore would not be granted a patent.

USPTO
U.S. Patent and Trademark Office, part of the Department of Commerce. The USPTO handles patent, trademark, service mark, and copyright applications, among serving other functions.

Venture capital
Capital invested by an investment company (referred to venture capitalists or VCs) that specializes in new or higher-risk business ventures. VCs usually prefer to actively participate in a new venture's management and share in its equity.