

## Who should benefit financially from a good idea?

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### ABSTRACT

The need to publish ideas so that they can be explored, debated and extended by others before they are fully tested in the lab or the clinic is in conflict with the need to patent those ideas to provide a commercial incentive to apply them. I discuss why this conflict occurs, why it is important, and suggest three ways to get round it: root-and-branch reform of patent law (which seems impossible), extension of the US system's 'grace period' between publishing and filing a patent to longer times in the US and implementing the same system in other countries (which seems unlikely to happen), and binding readers of journals with a network of optional confidentiality agreements that allow publication but not citation without the authors' permission. This latter appears too complex and conflicted an idea to work either. While many conflicts with common scientific practice exist, the complexity of the system need not deter us, as at root the idea is simple and so it could be managed by software instead of patent lawyers.

### TEXT

This journal has a dual purpose. Describing a new hypothesis has a public benefit, allowing others to build on the ideas presented, extend, enlarge or even correct them, and use them to stimulate new research to the benefit of mankind (1). But publishing an idea has a personal benefit for the author as well. They get the kudos of a paper in a respected, peer reviewed scientific journal. If their idea is recognised they get citations. Both of these personal benefits help to build scientific careers, and even for the authors who are not career researchers they provide gratification and recognition from the wider world.

In industry, however, this counts for little. The principle way that biomedical ideas are rewarded in a commercial setting is through the patent system, which gives the originator of an idea a monopoly on its exploitation for 20 years. The profit of the pharmaceutical industry is based in part on its ability to patent new drugs and hence charge monopoly prices for them, until the patent runs out. Publishing a paper on the effect of a Simvastatin is poor compensation compared to over \$10bn in sales that Pfizer makes from the drug, and over \$1bn profit in 2006 .

This is a problem for the biomedical sciences, because patenting a new therapeutic idea requires that the idea fulfil three criteria:

- Novelty. The idea must be novel, that is it must not have been described in public before.
- Utility. The idea must show some usefulness in itself
- Enablement. The description of the idea must include a description of how someone who is skilled in the field, but not necessarily a world-class expert, would realise it.

To be clear, the 'novelty' requirement requires that the idea has not been disclosed at all. Speculative disclosures, verbal descriptions in small meetings, sketches left on whiteboards, these all mean that an idea has been 'publicly disclosed' and so is not 'novel'. The only exception, which

we will come back to, is if you disclose an idea to someone under a formal ‘non-disclosure agreement’, which means that you agree the idea is confidential and you will not pass it on. Employees of a company are considered bound by such an agreement, and so can describe ideas to each other without losing the ability to patent. But if they describe the idea to their non-employee friend in the bar, or to their wife, then that is ‘disclosure’ and they have lost their right to patent. (It was rumoured that UK company Weston Medical had been blocked for a while from patenting its needleless injection device because the idea of injecting drugs without needles had been described before – on Star Trek, even though Dr. McCoy’s ‘hypospray’ was, obviously, a work of fiction.)

In the past, the ‘enablement’ requirement has often been met with theoretical descriptions. For example, a new class of drugs could be patented even none had been made, providing a convincing description of how it could be made was given in the patent. Increasingly patent offices are now requiring that actual worked examples of the invention be described in the patent. For a new therapy (a new drug or protein or cell) that means actually making and testing real examples. The irony of this system is that the patenting system does not reward the person who exemplifies the idea. The ‘inventor’ on a patent is the person who came up with the idea, not their postdoctoral researcher who spent long weeks or months in the lab reducing it to reality.

The patenting system is therefore incompatible with Bioscience Hypotheses (and our older sister journal Medical Hypotheses). We publish ideas before they are tested in the lab, or the clinic, so that others can build on them. But doing this means that they are no longer novel under patenting rules. So authors have two choices. The first is to publish the paper in one of the Hypotheses journals, and lose the ability to patent. The second is to gather enough data to demonstrate enablement, which will take time and cost money, patent, and then publish. This can take years, and does not allow anyone else to build on the idea until substantial time and funds have been invested in it. It means that some ideas are probably never described at all, because their originators wait for funds to take them to exemplification and patenting, and the funds never come. The fears in 1980s that patenting would stifle research were untrue at the time, but new rules means that it is becoming true.

Bioscience Hypotheses is founded around the philosophy that this secretive approach to innovation is unhelpful (2). Many minds are needed to create something genuinely novel, and many creative minds do not work in major research institutes where all the contributors can be found in one centre. However patents are a valuable tool to allow commercial development (and hence real world implementation) of innovation. So some way to bridge between idea and patent is needed.

Many universities and corporations operate such a system internally. They have a ‘statement of invention’ form, in which someone with a good idea can describe it so that it can be criticised and expanded by their colleagues and its potential commercial value assessed before any patent is filed. This works because describing an idea to your colleagues within an organization does not count as disclosure under patent law. This is fine for a major corporation such as Pfizer or GlaxoSmithKline with 10,000 scientist employees to discuss ideas, or the University of California with 170,000 staff and a core budget of \$3bn to explore and exemplify the idea. It is less useful to the lone inventor or student at a small college.

The US patent system contains a step in this direction. Unlike any other country, a patent may be filed in the US on an idea up to a year after it has been described in public. This is a ‘grace period’ after I describe an idea during which I can file a patent and still claim it is my intellectual property. So I can have an idea, publish it in Bioscience Hypotheses, get the input of others, refine it, and still file a patent (maybe with those others who contributed) providing I do all that in a year. Given the pace of innovation, this is challenging, but not impossible. It only applies to the US, but in applied life sciences this is still valuable as about half the world’s drug sales are in the US

But this is still a stop-gap, as the thesis on which we advocate publishing ideas before they are tested is that really creative breakthroughs are rarely the product of one mind, rarely applicable only in one country, and take years to develop and test. The input of others (starting , on occasion, with your editor (3)) adds, refines, extends and improves ideas, until at last something valuable, and potentially patentable, emerges from the end. Why should only the person with a big lab and lots of cash, and hence the resources to make the last step, be the only one to benefit? Why is the originator of this intellectual pathway not also rewarded?

In part, it is because there is a belief that finding out where an idea came from is terribly hard. Every idea is the offspring of many parents, and it can be hard to determine where the originating ideas leave off and the novelty appears. Indeed, the old adage has it that there are no new ideas, only variations on old ones . But this is an excuse. Most new, patentable ideas combine one or two specific novelties with a wide base of knowledge that is commonly held. Those specific novelties can be traced back to the inventors – that is what an ‘inventor’ is. If I publish an idea, and fifty people build on it to make better ideas, then I can claim intellectual property on my original one (but why would I, with all those better versions around?) or each of the fifty can claim their improvement, based on the demonstrated fact that my idea had become ‘common property’ to all those other thinkers.

What is needed, then, is a system for registering ownership of an idea before it is ready to be published, so that others can contribute, without ‘publishing’ the idea. This is quite distinct from the requirements for academic priority (for which the ‘*pli cacheté*’ concept has worked in the past and recently been revived (4)). Three options come to mind.

The first is to radically overhaul the worldwide patent system to include a two-layer process. The first step is a document that describes what the idea is, puts it in the public domain, but does not exemplify it. The second step is what today we would call a patent, with details of worked examples, which is based solely on the idea from the first document. The patent ‘clock’ – the exclusivity period that gives a patent its value – starts from filing the second patent. There need be no limit to the time gap between first and second documents, but there would have to be some mechanism for people who want to use the idea to force the inventor to file their final patent document or abandon their rights to do so – otherwise inventors could publish an idea and then block anyone else from doing anything with it for ever by the threat that they would file a patent one day.

But this will not happen, will it? The current law on intellectual property is embedded in the national laws of around 170 countries and the Paris Convention for the Protection of Industrial Property, which was first signed in 1883 and amended in many treaties since. Some countries only joined the community adhering to the standards and processes that convention and subsequent treaties in the last decade: The Russian Federation joined in 1995, Thailand in 2008. Changing all this seems implausible.

The second is to extend the ‘Grace Period’ in US patent law, and to implement a similar period in the patent law of other countries. Extending the US period would be very hard, as the US is under pressure to remove this anomaly from the international patent legal system. No other country has a similar mechanism. Introducing it elsewhere would probably therefore also run up against the impossibilities of getting 170 governments and the World Intellectual Property Organization to agree.

So a simpler, third route, albeit one that subverts the spirit if not the letter of existing law, is to bring all inventors into the fold of a single organization, so that our disclosures to each other have the same status as the ‘Statements of Invention’ that circulate within GlaxoSmithKline or UCLA. A

simple mechanism for this would be to bind readers of a journal under a non-disclosure agreement (NDA) that said that you needed an author's permission to cite their work in any other journal other than the one it first appeared in, and hence disclose the idea to someone else. Any subscriber would have to sign up the agreement before they received the journal, and downloader would have to click to sign up before getting the PDF. An author would then have a clear choice. Others within the community could read the work, publish papers on it in the same journal, write to him about it, even do experiments to test her ideas. But they could not publish the results except in a forum where it is read solely by people with an NDA with the original author without that author's permission.

If the author wanted to give up intellectual property rights, they could give permission for the contents of the paper to be described elsewhere, and gain citations and academic kudos as a result. If they wanted to keep their rights, they would refuse permission and lose citations as a result. The Journal would not like that (Impact Factor is a big motivator for editors and publishers) so they might insist on a right to part of the value of anything that came from a 'non-disclosed' paper.

This need not be on a publisher-by-publisher basis. Each journal could have its own agreement, each author on a paper a separate, legally binding non-disclosure agreement. Someone would have to keep careful track of who publishes what, who reads what, and where ideas are going. There would have to be better safeguards against downloading papers and then casually passing them on to others: at very least a download site would have to flag up a warning that if you, the reader, do this you are breaching your agreement and liable to damages. The resulting interlocking network of agreements and ideas and relationships would be enormously complex, probably as complex as airline booking databases or on-line supermarket fulfilment systems. That should not stop us considering their implementation, because such systems are now not only routine, they are routinely used by the general public with few mistakes. The days when a legal agreement had to be negotiated, drafted and enforced by human lawyers are long past. Software could enable such a system.

I must state that I am not sure that any of the three options above contain a workable idea, and that as stated none of them will work at all. The third does not need any changes in the law, and so is the most plausible, but needs contribution from many others before we could even consider its implementation. For a start, where does it leave the status of abstracts, currently freely available to all? But it is worth considering, because today's science is more interlocked and interdependent than ever, our understanding of biology is more complex and more in need of the intellectual input from many disciplines than ever before, but the need for intellectual property rights to allow the huge expense of applying biological understanding to deliver industrial products to yield commensurate rewards is also greater than ever before. If we do not find ways round this conundrum, we will find our science elegant, inspiring, and useless.

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## REFERENCES

- 1) W. Bains (2008) Many minds make light: Ideas and entrepreneurship in the life sciences. *Bioscience Hypotheses* 1(2), 65-66
- 2) W. Bains (2009) Hypotheses and humility: Ideas do not have to be right to be useful. *Bioscience Hypotheses* 2(1), 2009, 1-2
- 3) W Bains (2009) Evolution of a Journal. Editorial Policy 2.0. *Bioscience Hypotheses* 2(2): 57 - 58
- 4) Thomas C. Erren (2008) On establishing priority of ideas: Revisiting the “pli cacheté” (deposition of a sealed envelope) *Medical Hypotheses* 71 (1). 8-10