SCRIPT-ed

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Patients and IP – Should we care?

Patients and families affected by severe and chronic diseases tend to be interested in research and in the emergence of therapies that are targeted at treating or preventing the condition affecting them or their loved ones, but are often apparently uninterested in the issues surrounding and intellectual property that may arise from basic research and its translation into safe, effective, available and affordable therapies. If there is interest in IPR it sometimes takes the form of objections to the private sector profiting off the back of unmet health needs, or the idea of 'ownership' of our basic biology that are felt to be part of our common humanity. In my opinion patients and families cannot afford either to bury their heads in the sand about Intellectual Property, or to damn the system as the work of the devil and wish for it all to be done away with.

Why?

- IP is the system that has developed throughout the industrialised world to secure the transfer of innovative ideas into things that benefit people. Proper regulation of IPR will have a significant impact in determining whether or not his happens and how quickly this transfer takes place.
- Most health care needs remain unmet despite dramatic progress in the last 50 years. There is still a need to develop effective ways for preventing or curing many of the diseases that affect us. IP creates a framework for motivating people to invest and investigate in order to create novel products and therapies.

- We don't have to have IP –the 11th Commandment. Cuba has managed innovation without IP and developed a number of highly successful therapies for major health scourges affecting its population. But it is the system we have got, so we need to make it work in the context of the delivery of health care systems that are driven by concepts of equity and solidarity.

IP has been a relatively uncontentious issue in most areas of health care. Development of traditional drugs and devices present few challenges to conventional patenting practices, and health care systems are well used to dealing with the acquisition of novel products in these areas by negotiation.

Contentious issues arise in areas of cutting edge technology, especially genetics and biotechnology, where there has been fierce debate over technical applicability of patents – can a gene be described as an invention or is it a discovery, for example, or the ethics and morals of patenting something that it is impossible to invent around once a patent is granted.

It is not my intention to explore these issues – they have been chewed over extensively by people better qualified than me to no satisfactory consensus. In many ways the debate has been a dialogue of the deaf in that those who oppose biotechnology patents seem unwilling to shift from absolute opposition to the concept, whilst those who see them as legitimate are often equally intransigent in their views.

I suggest we should take a pragmatic view. The patenting and IP system exists. The real issue should be "How can we make it work to ensure the application of research to secure increased health gain?"

IP doesn't exist in a vacuum. It has a number of functions and the system operates in a context which is not unique to health care.

Proper management of IP can produce:

- Cost effective health gain
- Incentives for research and its subsequent application
- Development of industry
- A contribution to the economy of the country.

From a patient point of view a failure to capitalise on new knowledge or a system that only allows it to be brought into clinical service delivery at a disproportionate cost is more than a wasted opportunity. It means that a potentially preventable or curable condition remains untreated and avoidable ill health and suffering is allowed to continue.

Although the UK may be an island geographically, it is not an island in an IP context. International agreements such as TRIPS, and global bodies such as the WTO create frameworks that limit our freedom to act. The ability of investors to shift money around the world and place it where the regulatory regime offers the greatest prospect of a return on investment means that there must be a broadly similar level of IP protection across the developed economies of the world of investment is not to drain away from Europe into areas with more favourable regimes.

The passage of EU Directive 98/44 on the Legal Protection of Biotechnological Inventions has been the occasion for a debate that generated a great deal of heat and dust, but very little light. Protagonists for the Directive warned of an end to European

competitiveness and the death of the knowledge economy if it was not adopted, whilst those opposed to it prophesied rampant capitalist exploitation of health care and the widespread shutdown of public sector basic research due to restrictions of access to patented materials and a buccaneering approach to licensing and charging by the private sector.

What has happened since the adoption of Directive 98/44? To what extent have the fears espoused on both sides been shown to be real?

The Australian Law Reform Commission has recently conducted a most extensive survey of the impact of IP on genetics and biotechnology in health care. This review found that there was widespread anxiety in the academic and clinical communities about the potential impact of patenting, but little or no evidence of systematic abuse of patent protection by patent holders in ways that seek to limit research or constrain progress.

In practice, researchers seldom seek licences to use patented genetic materials, and patent holders seldom seek to prosecute researchers for possible (non-commercial) patent infringements. The ALRC could find little evidence of research being impeded in the vast majority of cases.

There are examples of aggressive patent protection creating problems. The case that everyone returns to time and again is that of Myriad and BRCA 1 & 2.

Even here, successful challenges have scaled back the scope of the company's patents dramatically, although this has been expensive and time consuming and the company is currently appealing and may yet be successful in getting its claims re-instated. However, the fact that other patent holders have not followed Myriad's model is perhaps a cause for optimism. The CF patent has been widely licensed. This has led to competitive improvement of diagnostic test kits by a variety of companies, improving patients' opportunities to get an accurate diagnosis and so to understand their situation better. An example of the IP system working well and producing real benefits for patients.

So, should patients worry if the system is not in meltdown, research is continuing and the health care system is managing – albeit imperfectly – to deliver a reasonable quality of service to families with genetic diseases?

Edmund Burke said that "all that is necessary for evil to triumph is for good men to do nothing". We cannot afford to be complacent. The patent system has some good and useful features, and patents are a useful currency in developing genetic and biotech applications in health care. They provide a degree of protection that is necessary given the longer time frame for development of medicines than in many other areas of innovation, and are a way of securing transparency in access to information that allows claims to be scrutinised and challenged and duplication of effort avoided.

Another important point to note is that the system is not static, and in the area of genetics and biotech standards for granting patents have been rising as more evidence for proof of utility and better defined claims are insisted on by patent examiners.

Whilst there are good features associated with patenting, the system clearly has downsides and disadvantages.

Patent holders currently rarely pursue infringements by researchers, but improved tracing systems might change this. Researchers may be surprised by the arrival of

unexpected invoices just as parents have found themselves being charged for illegal downloads by their children of music from the web.

Whilst patents are robust and transparent, licensing is murky and largely unregulated, and the granting of licences can lead to cost inflation and poor decision making if the cost of a license is seen as a cheaper option than the possibility of litigation in cases where the value of the IP in a previously granted patent is not immediately obvious and researchers are under pressure to meet deadlines and milestones.

There needs to be development of the methodology for granting licenses that are sensible and realistic and which serve the purpose of promoting the rational exploitation of novel innovations rather than simply rewarding the investor for having put money in the first place.

Innovative IP solutions such as the International HapMap project's Click/Wrap license need to be developed to meet a range of possible scenarios.

The HapMap data was intended to be in the public domain. In order to prevent someone taking it, adding something of their own and effectively privatising the lot through patenting or copyright the "click/wrap" license was used to control access on the basis of agreeing to the project's conditions of use. This provided an effective safeguard until the data was so ubiquitous that it would not have been possible to privatise it.

Where holders of IPR do seek the restrict access unreasonably there is a need for governments to make better and more rapid use of compulsory licensing procedures to prevent abuse of a monopoly position. This is especially important where patents involve gene sequences which cannot be invented around or where there is a significant health care issue that needs to be addressed the patent holder is blocking by his or her intransigence.

Other novel possibilities for preventing abuse by patent holders whilst securing a return for investors might include patent pools for a particular disease, or a "clearing house" for royalties similar to broadcasting rights payments. Both of these require trust and cooperation between all patent holders in a particular area of innovation.

Finally patents are a feature of market economics, and the market on its own will not generate a rational and equitable framework for directing innovation where it is needed with respect to unmet medical needs. Interventions to "tilt" the market place such as those provided by various orphan drug acts around the world have made development and therapies for rare disorders economically viable, whilst joint ventures between public, private and charitable sectors have brought new money into neglected diseases such as the Medicines for Malaria Initiative or the Global Alliance against TB.

Properly used and effectively policed, IP is a valuable tool for encouraging innovation in health care. However the system is not perfect and it is open to abuse, with substantial dis-benefits for patients as a consequence of this. Unless we remain vigilant the temptation fro some over-eager entrepreneurs to "try it on", taking a short term view and generating a quick profit rather than being in for the long haul may be too much of a temptation for some to resist.

"The price of freedom is eternal vigilance" – Thomas Jefferson this applies equally in healthcare as it does in other aspects of democratic life, and patients and families have a part to play in ensuring the effective, equitable and appropriate operation of the

system for managing IPR in the delivery of innovative healthcare and responding to unmet medical needs.

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