
Introduction

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On 12 April 1955, after eight years of research and testing, it was announced that Jonas Salk's polio vaccine was 'safe, effective, and potent'. The USA's 1916 polio outbreak had left 6000 Americans dead and another 27 000 paralysed (Mitka, 2005). In the two years following release of the vaccine, polio cases in the USA dropped by approximately 90%. By 1979, no cases of polio resulting from the wild virus were reported.

The immediate positive effect of Salk's research on the lives of thousands of Americans is uncontested. Yet despite its enormous success, the vaccine was not patented. When asked who owned the patent on the polio vaccine, Salk famously responded: "Well, the people, I would say. There is no patent. Could you patent the sun?" (Oshinsky, 2005).

Salk's explanation for not patenting the polio vaccine was probably not a legal argument – while he is right that no one can patent the sun, he may have been able to patent the vaccine (neither Salk, his university, nor the funder of the research ever filed a patent application in respect of the vaccine). More likely, his explanation is an ethical argument – that no one *should* patent the vaccine because it *should* belong to everyone, just as the sun does, and not to him, his university, the funder of his research, the company manufacturing the vaccine, or any one else. His argument might have been based on a belief that the consequence of a patent would have been to impede access to the vaccine, or that, according to moral principles, certain important, life-saving discoveries should be placed in the public domain.

Although half a century old, Salk's argument is still very much at play in research and medicine today. Both the consequences of patenting health-related discoveries for further research and for access to treatments and the morality of asserting ownership over certain kinds of discoveries – for example, those deemed life-saving or essential for ongoing research, or those deriving from the human body – are hotly debated.

The rationale generally provided for the patent system is that it is necessary to encourage innovation and the development of early stage discoveries. That is, that issuing patents on inventions and discoveries leads to the creation of new knowledge and new products. But this rationale is also contested, including by scholars, analysts, and practitioners who consider that in some contexts – including particularly biomedicine and biomedical research – patents sometimes do little to encourage innovation and can even impede access to products and slow future research (Mowery *et al.*, 2004; Heller and Eisenberg, 1998).

Nevertheless, in 1994 the vast majority of the world's governments agreed to amend their domestic legislation (where necessary) to protect intellectual property, including by providing for patents on 'products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.' This agreement, known as the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and signed by World Trade Organization members, has the important effect of somewhat harmonising patent laws around the world, including by eliminating exemptions from patent protection for pharmaceutical products, which some countries (including India) have used to secure affordable access to drugs.

The TRIPS Agreement does not make intellectual property rights absolute, however. It also includes mechanisms to protect public health, including the power to issue compulsory licences of patented inventions or discoveries and to import drugs purchased in other countries at prices cheaper than available locally. Implementation of the TRIPS Agreement and use of its public health mechanisms has proven complex and controversial, as three articles in this issue make clear.

In addition to international agreements, domestic law, policy and practice can affect how patents are used in, and what impact patents have on, biomedical research and treatment. In the USA, changes in domestic law, policy, and practice over the past quarter century have led to an increase in patents filed by academic institutions. Although some academic institutions had sometimes sought patent protection for the inventions and discoveries of their research staff, it was not always clear whether institutions should seek such patents. In 1980, the US federal government passed legislation making it clear that research institutions can patent the results of their government funded research and license their inventions to industry for further development.

Since then considerable debate in the USA has focused on the impact of academic patenting on the university environment and the progress of research. The coincident emphasis on biomedical research in the USA, including through the National Human Genome Project, makes this policy and these debates particularly relevant to human health. The fourth article in this issue explores the changes in US law, policy, and practice and the controversies it has engendered, noting that lessons learned in the USA can be important for other nations formulating or beginning to implement similar policies.

The role of patents in biomedical innovation and their impact on access to treatment is complex. While the case of the polio vaccine is clear enough (the promise of patents did not play a role in motivating vaccine research and development), the story of the polio vaccine is not the story of all new drugs and treatments, many of which use patents to secure commercial investment at all stages of their development, including the expensive step of bringing them 'from bench to bedside'.

On the other hand, the polio vaccine model is not entirely unique or outdated, either. Governments and charities today provide considerable funding for research and drug development in cases where patents, and eventual markets, do not provide sufficient financial incentives. In fact, there is not one model for the funding and conduct of biomedical research or the development and provision of treatments, and there is not one model for the optimal role, if any, of patents in these processes.

To further complicate matters, patents are but one of the potential barriers to access in biomedical research and treatment. While there are examples of medicines – particularly those for AIDS – that became far more accessible when the political focus was put squarely on the link between patent monopolies and the price of the drugs, it is also clear that an absence of patents does not necessarily solve access problems. Despite the decades-long existence of an easily administrable and inexpensive (unpatented) vaccine, polio has persisted in many nations. In 1988, the wild poliovirus was still endemic in more than 125 countries on five continents, paralysing more than 1000 children every day. It was not until early this century that polio cases were reduced to an estimated 800 children per year worldwide (WHO, 2003). The low cost of the vaccine – there was never any patent or any need to recover the costs of research and development – was clearly not enough to ensure universal access. Today, many in the world do not have access to essential drugs despite those drugs being available at little or no cost. Political will, health care infrastructure, and culture, among other factors, can all impact access.

The articles in this special issue result from a research project funded by *The Sasakawa Peace Foundation* and conducted at *The Hastings Center*, an independent bioethics research institute in Garrison, New York, USA. That research project sought to survey the ethical and legal debates over biomedical patents, to consider how patents can impact access to research inputs and to HIV/AIDS medications, and to explore mechanisms within and outside the patent system for addressing any patent-related access problems. A report on this project is available from The Hastings Center website. These four articles provide a detailed consideration of some of the debates as they play out in particular countries, regions, or sectors.

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