PROMETHEUS
2017, VOL. 35, NO. 3, 231–236

Routledge
Taylor & Francis Group

REVIEW ESSAY

Research handbook on intellectual property and the life sciences, edited by Duncan Matthews and Herbert Zech, Cheltenham, Edward Elgar, 2017, 528 pp., £180 (hardback) ISBN: 978 1 78347 944 3

Introduction

Research handbooks aim to give an overview and insight into the current themes for research in a subject area, as conceived by a subset of its current scholars. The typical parameters are: topics regarded as prominent or newsworthy, the network of academic contacts within the editors' frame of reference, and whatever may be regarded as the normative set of principles and ideologies of that group. As far as its biomedical and product-oriented focus permits, this handbook fulfils its role as a snapshot of those topics current in the discussion of intellectual property (IP) and the life sciences, particularly biogenetic research. Eight of the 27 articles have been authored by female scholars which, while well short of the natural gender distribution, at least demonstrates progress of some kind. The more technical articles provide a good summary of recent changes in legislation, and useful comparisons between the EU and the USA. From an international perspective, Part IV is a concise survey of the status and impact of current IP law in a selection of seven countries: Brazil, China, India, Japan, Kenya, South Africa and Thailand. Functional aspects of the local IP regimes are addressed as well as the key political, social and ethical implications, such as the HIV problem in South Africa. The effect of the TRIPs agreement is not neglected. These articles are hardly exhaustive, or definitive, but provide a cross section and a set of references for those wishing to engage further.

A research handbook authored by scholars of the law must be expected to approach a subject from a different perspective from that of a group of economists, historians, philosophers, political academics, and scientists. 'Intellectual property' as a term gained momentum only in the late twentieth century to help steer the status of ownership of ideas in the direction of the long-standing legal framework around property rights. Yet, perhaps because the concept of property ownership remains at heart a controversial topic, discussion of intellectual property sways back and forth in journals as much as in court. The dynamic, political nature of this discussion is compounded in the case of IP for the life sciences, where the ground constantly shifts and technological advances are likely to raise new points of reference and bury others. It will probably not be long before some of the material in this book, and some of the commentary in this review, is rendered redundant. As this review was being prepared, a paper published in *Science* (Hirota *et al.*, 2017) describes a significant breakthrough in the editing of embryo DNA by the Francis Crick Institute in London. As we get closer to the point of gene editing, ethical issues are likely to become even more prominent in the legal discussion of life sciences

Swinging pendulum

The paper by Ghosh (chapter 4), referring to the 'patent friendly environment' of the 1970s and 1980s, reminds us of the way in which the private–public legislative pendulum swings. An example of the swinging pendulum is shown in Rimmer's excellent (and thorough)

paper (chapter 5) on the BRCA1 cancer mutation. Myriad Genetics performed a useful service by developing a proprietary test to identify a mutation in gene BRCA1 that indicates susceptibility to breast cancer, but its business model was to charge a premium for the test and its licence, aggressively excluding other laboratories. The consequence was an enormous and rapid increase in the firm's profits and share price. But Myriad has since encountered difficulty with decisions in the USA and in Australia, where the courts considered the patent's long-term implications.

It is important to note here that, while the test was Myriad's, identifying the BRCA1 gene and protein was a collaborative project involving such public non-profit institutions as UC Berkeley, the University of Utah, the US National Institutes of Health (NIH), and McGill University. As the Colombia University website observes (in putting forward the contribution of its own Erwin Chargaff), the Eureka moment in science (discovering the structure of DNA, for example) 'often occurs as a result of putting together findings made by many other contributors'. It is not unreasonable to argue that the long list of contributors to Myriad's windfall goes back at least 150 years to Darwin and Wallace. Along with Chargaff, names that stand out in the 100 years before 1960 include Mendel, Miescher, Garrod, Levene, Morgan, Avery, Franklin, Schrödinger, Watson, Crick and Lejeune, the great majority of these associated with publicly funded non-profit institutions. Recent history is hardly different; all current biogenetic work makes use of data produced by publicly funded research. Take the Human Genome Project: its costs exceeded $US3 billion, the majority of which was public money from a variety of US non-profit agencies, the balance (£150 million) coming from the UK's Wellcome Trust (Gannett, 2008). These estimates do not include public investment in educating the researchers to doctorate level.

What is life?

This essay collection is of special importance to the discussion of intellectual property because the areas of science and technologies it addresses include the word 'life'. The proportion of women who have access to an affordable test for breast cancer, or the proportion of a population that has access to a treatment for any life-threatening disease is a question of more immediate concern to individuals than access to the latest features of a smartphone. Intellectual property is important, the Introduction explains, because a high level of investment is required for developing new technologies and products, and because 'IP rights are intended as instruments to provide incentives for investment'.

In one sense, all sciences, in fact all human activities, bear upon life because the ownership of property and the responsible use of it is of mortal importance to us. Scotland's 7:84 Theatre Company was launched in 1973 with an impassioned musical polemic called *The Cheviot, the Stag and the Black Black Oil*. Its subject was the Highland Clearances, a dark period in Scottish history that recalls the devastating failure of some large estate owners to solve the demographic, economic and social problems of their population through innovation, preferring in many cases to dispossess tenant families (condemning them to starvation or emigration) and converting thousands of acres to sheep farming or game reserves. The theatre company's name was drawn from an *Economist* statistic from 1966, which showed that 7 per cent of the UK population owned 84 per cent of its wealth. Strikingly, 50 years later, that disparity in wealth distribution seems to remain.

Property rights, the argument runs, are the most efficient means of making use of a scarce and valuable resource for the benefit of society, based on the assumption that the

owner of a property has the greatest incentive to seek the maximum return from it, presumably through invention or innovation. One problem is that, where rent is found to be benefit enough, ownership of property may not always be accompanied by an incentive for innovation and, as the Highland Clearances suggest, one person controlling a vast amount of property may make decisions about its disposal that have shattering, life-changing consequences for many. Ownership of property and distribution of the benefits may become grossly skewed. For this reason, we acknowledge that property rights cannot be absolute and the general good may sometimes be served by setting them aside, using such instruments as compulsory purchase orders (or eminent domain), easements, zoning laws, rules against perpetuities and restraints on alienation.

We do not expect wealth distribution to be precisely equal, but we observe that aggregation and hereditary ownership may allow extreme disparities to grow and to persist across many lifetimes. When, in 1999, a Labour government evicted the hereditary peers from the House of Lords, among them were no fewer than 49 heirs of the Plantagenets, a family supposedly removed from power with the death of Richard III in 1485 (Cahill, 2002). Over 500 years later, 20 of these ancient peers were on the *Sunday Times* rich list for the year 2000 and nine were among the top 30 landowners in the country.

Artificial monopolies

The owner of an estate has the exclusive right to grow crops on it, to let it lie fallow, or – perchance – to shoot deer on it. Not merely the right, but the exclusive opportunity as its sole occupier. This is true of real estate, but not of ideas. Plant (1934) observes that 'rights in patents and copyright make possible the creation of a scarcity of the products appropriated which could not otherwise be maintained'. We create artificial monopolies through law that are intended to encourage the inventor or entrepreneur by ensuring that the economic benefits of their work will accrue to them. At the same time, we are aware that the monopoly has a cost in that it may prevent others, for varying periods, from independently exercising their creativity on that idea. Since, as Hume observed, 'the good of mankind is the only object of all these laws and regulations', it follows that we ought to be particularly careful to find out to what extent monopoly rights in the life sciences have been effective in encouraging investment, what areas of technology have proved to be the most attractive to investors, what useful technologies or products have emerged, and how and where the benefits are being distributed. Subsidiary questions include whether the current IP system may have negatively affected investment or development work in some areas (the unknown unknowns problem) and whether any alternative to the patent system might have been more productive.

Given our natural concern about monopolies, it is unsurprising that the core of the handbook is the court's struggle to preserve a balance between the rights of the inventor to recover economic benefit from her work, and the benefit to the public of having free access to the invention. The consequence of this private-public argument has been a continual adjustment, swinging between corporate interests and public. References to the landmark cases are sprinkled across the pages: Alice, Chakrabarty, Mayo, Myriad and Prometheus. Heller and Eisenberg's anticommons theory and various critiques of it appear more than once, though McManis and Yagi's piece (chapter 15) on Bayh-Dole seems to come down against the theory in finding little evidence that early patenting by universities retards biomedical innovation. Opinion surveys, cited to show that 'patents have rarely blocked academic research' are open to two objections. First, to explain this by saying that scientists 'are oblivious to the patents they may be infringing' and that patent owners 'would not find

it cost effective to sue' would seem to undermine the entire patent system. Second, we really have no useful way of measuring the conscious or subconscious level of deterrence. A non-profit institution may steer clear of an area of genetic research since it is aware that the area overlaps another area attracting the close attention and substantial resources of multi-national corporations. Will decisions like this appear in any record? Van Overwalle (chapter 17) insists that the 'hypothesised tragedy of the anticommons did not manifestly occur'. There is no record of the loss of collaborative sharing, communication, freely distributed information and tools. How can a total absence be made manifest?

The first problem for basic research is the difficulty in getting resources. Figures suggest that between 10 and 30 per cent of all research applications in the UK receive funding. The majority of funds are more likely to go to 'product'; that is to medical and short-term projects whose benefits are easier for the civil servant or politician to perceive and explain. We know that mathematical research projects are rarely, if ever, funded, since explaining the value of solving a major theorem makes no sense to most people until its application becomes apparent 50–100 years later. (Hamilton's quaternions conceived in 1843 are only recently finding a use in 3D computer graphic calculations.) It is hard work to generate public enthusiasm for supporting apparently long-term, arcane and uncertain outcomes. The focus on products and technologies means that long-term knowledge-oriented research is pushed to the back of the queue, but even research with intermediate-term impact outside the field finds it difficult to acquire funding.

Given the justification of IP as a facilitator of investment, it is inevitable that this collection of papers seems to favour the discussion of IP for biomedical products and services as opposed to the kind of knowledge research that is hard to validate in the short term, but from which most truly great insights have emerged. It may surprise members of the public to know that some of the research which generates the greatest public interest, such as evolutionary biology (where chimpanzee and gorilla genome mapping recently made headlines), is often the hardest to fund. In contrast, research with more immediate medical or agricultural relevance is much easier to fund. The papers in this handbook tend to reflect commercial and corporate interests rather than any public thirst for knowledge. R&D is essential for pharmaceutical firms hoping for future product lines, while stock markets, shareholders and pressure on the bottom line make any uncertainty very difficult to defend. Firms will incline toward the low-lying fruit, investment in the shorter-term project with clearly articulated benefit, or projects where the path is clear.

For many non-profit researchers, added to the time and energy spent begging for funding comes pressure from the university's technology transfer unit to spend more precious time pursuing patents. At government level, Plomer's paper (chapter 13) on stem cell research points to the pressure of current EU policy toward procuring IP on funded projects and to maintaining an element of secrecy. The questionable economic value of retained IP to universities is not examined here, but, as Plomer points out, EU policy is 'liable to frustrate scientific research and stem cell science as a co-operative venture for the public good' by prioritising patents over publication, encouraging the withholding of publication and minimising reporting requirements between project collaborators. It may be that the EU takes the view, as a Wellcome Trust researcher once explained to me, that non-profits should patent as a means of protecting, or ringfencing, areas for future research. This cerebral version of the Oklahama land rush runs counter to just about all the principles of classic scholarship.

The collaborative nature of scientific research is counter-intuitive for most of us, since we live in a world with an innate tendency (reinforced at school and in business) to ascribe the

creative spark to a single inventor – the lone genius. Thus, the theory of evolution is 'Darwin's theory', although at least two of his contemporaries arrived at similar conclusions; the discovery of penicillin belongs to Alexander Fleming, though the Nobel prize for this was shared with Florey and Chain, and should have included Heatley; the internet has many creators, though an effort has been made to designate Vinton Cerf as its 'father', and it is clear that the technologies we now enjoy are the products of creative and technical minds beyond number. A typical research paper on genetics might have contributors from 20 organisations in many countries, each funded by separate organisations. Science is, above all, the most truly collaborative venture.

When the Human Genome Project was finished, and a full genome map was available, the product race was on. As Minssen (chapter 3) observes, its completion 'made it much more difficult for many biotechnological inventions to meet novelty requirements'. Presumably there was little real mystery about the next steps, the identification of genes and proteins responsible for, or indicating, diseases and pathological conditions. And perhaps there was also a significant degree of obviousness about the methods for working out how to do this.

The corporation versus the patent system

A recent *New York Times* report describes the transfer by Allergen of patents on *restasis*, an eye drug, to the Saint Regis Mohawk tribe in upstate New York. Because the new 'owners' of *restasis* are an Indian tribe, they are able (at least for now) to claim sovereign immunity from challenges to the patent. For a fee of $US15 million, Allergen thus protects its lucrative monopoly from a challenge by Teva Pharma, a generic drug producer. Teva described the move as a 'new and unusual way to try to delay access to high-quality and affordable generic alternatives'. More matter for the court and the legal profession.

A large firm can apply its substantial resources to delaying public access to its most profitable inventions. It may find many ways to circumvent the awkward IP system that Fisher (2001) describes as 'a loose cluster of legal doctrines'. This handbook does not explore alternatives, but does point to the pathologies of the present system, and, in an area as urgent as life sciences and genetics, emphasises the urgency of fixing such an awkward system.

There is a further consideration about obviousness and inventiveness. Computer-aided design systems are likely to become more powerful and capable of inventing drugs, circuits and mechanisms without human intervention. Invention then becomes little more than the result of someone skilled in the art using its tools. What non-obvious invention is going on when a computer sifts through a million candidate chemicals, finds 20 to run through robotic testers, and narrows these to the handful of candidates to be tested by humans? The final testing has so narrowed the discovery space as to make the outcome obvious.

We need the products and we need the innovation, though often the steps taken by a corporation to achieve a product or service are not particularly novel or inventive. It seems a terrible waste that, in order to incentivise a corporation to produce a small innovative step, citizens must surrender the fruits of 200 years of publicly funded education and research, and run the risk of locking it all away from future researchers.

References

Cahill, K. (2002). *Who Owns Britain; the Hidden Facts behind Landownership in the UK and Ireland*, Canongate Books, Edinburgh.

Fisher, W. (2001). 'Theories of intellectual property' in Munzer, S. (ed.) *New Essays in the Legal and Political Theory of Property*, Cambridge University Press, Cambridge.

Gannett, L. (2008). 'Genes and society' in Ruse, M. (ed.) *Oxford Handbook of Philosophy of Biology*, Oxford University Press, Oxford, pp. 451–57.
Hirota, T., Ohta, H., Powell, B., Mahadevaiah, S., Ojarikre, O., Saitou, M. and Turner, J. (2017). Fertile offspring from sterile sex chromosome trisomic mice. *Science*, 357, 6354, 932–35. doi:10.1126/science.aam9046
Plant, A. (1934). The economic theory concerning patents for inventions. *Economica*, 1, 1, 30–51. doi:10.2307/2548573

Kevin Scally
University College Cork, Ireland
K.Scally@ucc.ie

https://doi.org/10.1080/08109028.2018.1518694