Cover page

Dr. Catherine Rhodes (Corresponding Author)
catherine.rhodes-2@manchester.ac.uk
Tel. 0161 275 4709

Prof. John Harris
john.harris@manchester.ac.uk
Tel. 0161 275 7074

Ms. Sarah Chan
sarah.chan@manchester.ac.uk
Tel. 0161 275 0904

Prof. John Sulston
john.sulston@manchester.ac.uk
Tel. 0161 275 7074

All at:

Institute for Science, Ethics and Innovation
School of Law
Williamson Building
The University of Manchester
Oxford Road
Manchester
M13 9PL

The 'Ownership' of Science

Catherine Rhodes*, John Harris, Sarah Chan and John Sulston

Institute for Science, Ethics and Innovation, University of Manchester, UK

* Corresponding author: catherine.rhodes-2@manchester.ac.uk.

We are interested in the growing importance of intellectual property (IP) and its effects both positive and negative on the progress of science and innovation. The first section of this paper is a consensus document - "Who owns science?", aka the Manchester Manifesto - that was produced by a working group meeting at iSEI. The document elicited a variety of responses, including an exchange with the Chartered Institute of Patent Attorneys; review of these forms the second section of the paper.

The Manchester Manifesto is not anti IP, but it does ask to what extent IP is helpful in the delivery of important public goods and services that are essential for human flourishing, and what changes should be made to correct any shortcomings.

This is not the first, and certainly will not be the last, discussion of the merits of IP. Debates are often highly polarised, as can be judged below, but we hope that the responses in Prometheus will lead to a broadening of the dialogue – particularly on how to move towards more appropriate management of innovation.

Because IP lies at the heart of the 'knowledge society' there is a widespread unwillingness to consider any problems, and indeed great resistance to any idea that reform is needed. Furthermore, it is frequently said that strengthening of IP is always good and is essential for promoting innovation. But actually some evidence points the other way. For example, the first green revolution, which averted mass starvation for a generation, was conducted in the public domain, motivated by goodwill and its products were distributed freely. By contrast, it is unclear whether the much needed second green revolution will be as successful, if it becomes bogged down in conflicting IP claims and leads to expensive products.

The existing system of IP was built on exchanges between knowledgeable and consenting trading partners on a fairly level playing field, under which circumstance it serves a useful purpose. However, it has subsequently grown unchecked without serious examination of the effects. Notably, in a highly unequal world the existing system exacerbates inequities in health and wealth, so that the fruits of science are enjoyed mainly by the rich. Further, despite its merits on a small scale among well matched trading partners, strong IP is unhelpful for the massive global problems that we collectively face in resource limitations and climate change. These are zero sum games in which aggressive competitiveness is counterproductive.

We appreciate that necessary reform of the IP system will not take place on a unilateral basis, and will need collective efforts from all actors involved in the innovation process to ensure that science can fulfil its potential for promoting human flourishing and responding to major global challenges. This cannot be done without addressing the issues of inequity that are inherent to the current system. We cannot afford for innovation to remain overwhelmingly concentrated in a few developed nations.

THE MANCHESTER MANIFESTO

(Institute for Science, Ethics and Innovation, 2009)

Introduction

Science, along with the innovation it generates, is a vast enterprise: commercial and *pro-bono*, public and private, industrial and educational, amateur and

professional. It permeates our lives and shapes the world. Some say it is a defining characteristic of humanity, stimulating and harnessing our innate curiosity and, more than any other endeavour, shaping our world and, increasingly, ourselves.

For many reasons, some of which are set out below, it is increasingly important to consider the question of "who owns science?". The answer to this question will have broad-ranging implications: for scientific progress, for equity of access to scientific knowledge and its fruits and for the fair distribution of the benefits and the burdens of science and innovation – in short, for global justice and human progress.

Our approach

The Manchester Manifesto Group brought together international experts from relevant disciplines to address the question of "Who Owns Science?" Led by two research institutes at the University of Manchester, the Institute for Science, Ethics and Innovation and the Brooks World Poverty Institute, the Group represented a critical mass of research expertise equipped to meet the challenges and problems outlined above. The Group's members[1] were drawn from a broad range of academic disciplines and relevant sectors, including economics, science, innovation, law, philosophy, ethics and public policy. Our goal is not only to investigate the question of who owns science but to present and apply our findings to maximum effect in order to make a difference in the real world as to how science is used.

Statement of the problem

Science is a rapidly growing industry. Beyond basic research, the commercialisation of technologies and development of new products from bench top to marketplace is a complex process. In asking "Who Owns Science?" we are concerned with all aspects of this process: scientific discovery, development, application and distribution; and the interactions between each aspect. The way in which this is managed, and in particular the way in which access to technologies is facilitated and controlled, is having and will inevitably have an increasing impact on the course of science-based technological innovation.

An important component of the innovation process has been the idea of "ownership" in science and technology. This concept has arisen partly in the context of profiting from research and development, but also has implications for much broader issues such as control of and access to scientific information and products that result from research, in terms of both the private and socio-political dimensions of ownership.

To manage the ownership of science and the fruits of research, an intricate system of intellectual property (IP) law has developed. The justifications for IP law as it exists at present include the idea that it is required in order to facilitate scientific and economic benefit from innovation, and that it provides a fair and morally justifiable way of rewarding those who invest in the process of discovery and regulating access to these benefits.

The initial meetings of the Manchester Manifesto Group in 2008-2009 established that the current method of managing innovation (and perhaps in particular IP in its present form), whilst deeply embedded in current practice and hence of practical

importance, also has significant drawbacks in terms of its effects on science and economic efficiency, and raises ethical issues because of its (often adverse) effects on people and populations.

The Manchester Manifesto Group considered the core goals of science and identified various issues and problems with the current system of ownership and management of science and innovation, highlighting elements that hinder or obstruct achievement of these goals. Reflecting on these problems, we were able to articulate some broad principles and policy considerations to guide any investigation or evaluation of alternative systems of innovation. Finally, we outlined some questions that must be addressed if we are to move towards solutions to the problems identified by the group. We call for further research in these areas as a matter of great importance, in order to answer the question not only of who owns science, but of who *ought* to own science and how the goals of science can best be fulfilled.

The scope of this document is largely concerned with science that is in the public interest. More thought must be given to how we characterise what *sort* of science is in the public interest, and how we draw the boundaries between "public" and "private" science, in both the practical and the normative sense.

Goals, Problems and Issues in Science and Innovation

Goals

Science and the public good

Science can serve the public good by generating knowledge to meet human needs and purposes. This includes knowledge with direct application to current challenges and pure/undirected endeavour (so called "blue skies" research) that forms the essential basis for future scientific discovery.

- The pursuit of pure (unapplied) scientific research is clearly in the public interest, since curiosity expands knowledge, which is in itself a good thing. This justifies investment in such research.
- Science-based technological innovation further serves the public good by playing a key role in economic growth and development.
- There is a basic public interest in access to knowledge.

Reciprocal responsibilities of science and society

The relationship between science and society is essentially one of reciprocity, mutual benefit, and needs to be seen to be so. Just as science has responsibilities to the public good, the public has responsibilities towards science as the collective recipient of its benefits and as a major funder of its activities – a relationship that is often mediated by policy:

- Public confidence in and engagement with science is vital; openness to public scrutiny can help to maintain trust and support. Science should be open to the public, enabling understanding of its purposes and implications.

- Society needs to provide just and effective conditions for the increase of scientific knowledge. Any management mechanisms should be justifiable, appropriate, and built on a sound understanding of both science and the systems in which it operates.
- To achieve the goals of promoting scientific progress and human welfare, the scientific community has a responsibility to facilitate reflection of scientific understanding in policy, and should seek participation in policy-making processes and debates at the national and international level.
- Policy-makers need to ensure that there are opportunities for voices from the scientific community to be heard. Scientists and policy-makers have a joint responsibility to ensure this participation occurs in a transparent manner to avoid public suspicion of undue influence.
- Policy-makers should also ensure that there are opportunities for the voices of the public to be heard.

Innovation and the public good

Management of innovation has significant implications for scientific progress and human welfare. It affects the distribution of benefits, access to technology, dissemination of knowledge, and the pace and direction of research.

- Innovation should operate for the public good, amongst other goals.
- Given their efforts and investments, the scientific community and the public can also be viewed as 'shareholders' in innovation, and its benefits should remain open to them (in the form of welfare goods and knowledge).

Issues/Problems in the Current Management of Innovation

The interests and contributions of inventors and authors deserve to be recognised fairly. However the current dominant model of innovation and commercialisation of science poses a number of problems. It has potential to encourage innovation and stimulate research and development, but also to frustrate innovation and stifle research and development; and can hinder science from operating in a way consistent with the public good.

Access to benefits of research

Current models can restrict or prevent public access to the benefits of research – both the information generated by scientific endeavour and the products of innovation based on that science – and thereby hinder science from serving the public good.

- Certain licensing and commercial practices can restrict access to the products of science and innovation, particularly for those with limited market power.
- This is of particular concern in the case of those products that address basic needs (such as health care).
- The current model rewards particular kinds of creative effort, namely those which result in commercial gain. It is therefore likely to hinder innovation of products that have limited market value, but which may have huge social benefit.

- The obligation on corporate innovation to maximise profit and return for shareholders can conflict with the creation of knowledge and achievement of welfare goals.

Effect on innovation

Current models can hinder innovation because:

- Certain licensing practices can have restrictive effects on innovation. These include, for example, use of very narrow or exclusive licence terms.
- The increasingly common incidence of requiring multiple licences for the use of a single technology or research tool complicates access, making it more costly and time-consuming.
- Perceptions of accessibility problems can lead to enterprises deciding not to attempt to apply for licences.
- New business entry into innovative industries is very difficult due to the high transaction costs involved in operating in an arena of multiple intellectual property rights, reducing competition and allowing large companies to dominate markets.
- Navigation and implementation of the patent system, negotiation, bargaining and litigation require costly expertise.
- The operation of the current system often prevents the holders of IP rights themselves from realising the full benefits of these rights, for example because of the costs involved in asserting them.

Scientific progress

- Restrictions on access to information at any stage of the innovative process obstruct the flow of scientific information and thereby impede scientific progress. Such restrictions are also contrary to the needs of scientific inquiry and are inimical to openness and transparency.
- Information sharing among the scientific community can be reduced or suffer from delays as a result of patent requirements (e.g. that information must not be in the public domain at time of filing).
- The complexity of the system creates uncertainty, for example over researchers' ability to obtain necessary licences, which can discourage investment in research and development.
- These access restrictions have particularly severe effects on public, not-for-profit, small and developing country enterprises, which cannot afford the expense of licences and/or the expertise required to navigate the patent system. This can obstruct, delay, or entirely shut-down valuable lines of research and innovation.

Overall, the current patent system is self-reinforcing, encouraging proliferation of patents and multiplying these problems.

Broader Issues

There are also broader issues resulting from the dominant model of innovation which should be given consideration.

- Improving systems of innovation may not be enough in itself to promote human welfare; there is also the problem of insufficient capacity, particularly in many

developing countries, to access scientific information, operate and navigate innovation systems, and achieve access to innovative products e.g. because of weak health infrastructure.

- The transition from basic science to product in the clinic or marketplace is not always linear and unidirectional. The relationship between 'pure' and 'applied' research, science, technology and innovation is a complex and multi-faceted one, with interactions between actors at all stages influencing the process. The effects of action/regulation in one area may have implications extending across other aspects, and each area may have unique issues and problems associated with its management.
- Within this process, actors can have multiple roles, creating potential conflicts of interest. For example, a single individual may have both scientific and commercial interests at stake; governments may face a conflict between stimulating economic development through rewarding private investment in research and optimising the public benefits of science.
- In many cases, profit has become the primary reward for research and development – often to the point of other drivers of innovation dropping out of consideration. Greater consideration should be given to different drivers of science/incentives for innovation beyond profit.
- It is not only the intellectual property system that restricts participation in innovation; there is also all too often a lack of strategies to encourage openness of communication, participation in research, and sharing of information and products that result from science and innovation.

Global Dynamics

The global context in which science and innovation now operate and of which they are an integral part needs to be given consideration, because it also affects their operation and effectiveness. While states have the sovereign right to adopt their own rules, laws and procedures, they need to operate within the bounds of a variety of international rules and norms and with awareness of international dynamics. For management of innovation, these include:

- Permeable national boundaries creating high mobility of knowledge, materials, and personnel, and meaning that the impacts of national policies may be widely felt in other states.
- In areas which lack harmonised international regulation, innovative activities can migrate to territories in which regulatory regimes are weak or non-existent.
- Frequent prioritisation of national interest and economic competitiveness by states in their international relations.
- Wide disparities between rich and poor within and between states, in terms of income, opportunities, health, education, and access to science, technology and the products of innovation.

International regulation has advantages in its ability to harmonise national policies, providing clarity and reducing the costs of compliance. It must be recognised, however, that international regulation also has disadvantages. Powerful states have greater influence in rule-setting and less to fear in regard to the consequences of non-compliance. Commitments to capacity-building for developing states are inadequately fulfilled and enforcement is problematic.

Additional problems occur at the international level:

- Diverse national regulation of innovation creates complexity in compliance. This can increase costs to innovators, pushing publicly funded, not-for-profit and developing country enterprises out of international markets.
- International regulation can have the effect of privileging the interests of wealthy states over general human needs due to power imbalances.
- International regulation currently remains state focused and often reinforces state sovereign rights. It can therefore be of limited effect on transnational actors (e.g. corporations) and often promotes national interest above that of local communities.
- Bilateral agreements and 'free trade areas' are being used to impose excessive and inappropriate standards on less developed countries.

The effect of the current international rules, which set minimum standards for intellectual property protection, is that a single model of intellectual property protection dominates, and at the same time is operative in many national systems. This dominant model is intended to promote scientific and economic development, but can be radically flawed in this respect. Alternative models need to be promoted and existing flexibilities fully explored to ensure innovation can meet welfare goals.

Principles, Policy Considerations and Progress

We recognise that innovation has an essential role in economic development, but its use for the pursuit of profit should not override, and ideally should not conflict with, achievement of welfare goals and scientific progress. Scientific information, freely and openly communicated, adds to the body of knowledge and understanding upon which the progress of humanity depends. Information must remain available to science and this depends on open communication and dissemination of information, including that used in innovation.

Management of innovation is one of the routes through which public benefits of science can be realised. This requires a range of appropriate policies and regulatory mechanisms developed in cooperation with scientists, innovators and the public, combined with awareness of the implications of pursuing particular models of innovation management.

Advantages and disadvantages of these models need to be carefully assessed in regard to their cumulative impacts on the innovative process, achievement of welfare goals and scientific progress. Current systems for managing innovation may require adaptation and incorporation of greater flexibilities. In addition, consideration of alternative systems is needed.

Principles

The regulation of frameworks of innovation should promote the following objectives:

- Provision of public benefit
- Just recognition of interests
- Facilitating progress of science and innovation

- Increasing access to fruits of research – information and products
- Addressing welfare and resource inequities both locally and globally
- Increasing trust in the relationships between scientists, innovators, corporations and public, and between nations

At times these objectives may conflict and attention must be given to the most appropriate way of balancing them in each situation.

Policy Considerations

Alternative systems

The current dominant model of intellectual property rights for innovation is not the only option available. There are existing alternatives and new models can be designed with differing cost distributions. Different systems may be appropriate in different areas; consideration must be given to the factors that affect this, including the nature of the knowledge, the method of discovery and the environment in which knowledge generation takes place.

For example, the current system can be modified through increased use of mechanisms such as patent pools, voluntary or compulsory licensing, and differential pricing. A range of alternative models is also possible: from those which are related to the current rights system such as remuneration-based patents, through prize funds, to completely open-access models.

Assessing models of innovation

Any model of innovation is likely to have advantages and disadvantages. Consideration should be given to which is the most appropriate for particular circumstances, bearing in mind the principles above and the goals of science and innovation.

In evaluating the various possible models, the following factors should be taken into consideration:

- The extent to which it advances welfare and promotes human flourishing
- Fair and equitable distribution of benefits and burdens, with particular attention to resource providers (including the scientific community, the public, specific contributors of knowledge/biomaterials, and other contributors)
- Facilitation of safe and sustainable access to the end product
- Affordability in use of the system and of the end products
- Maintenance of free flow of scientific information
- Promotion of open communication
- The provision of adequate incentives to stimulate scientific discovery and innovation
- Ease and effectiveness of operation
- Inclusion of operational rules appropriate to achieving desired objectives
- Awareness of global dynamics

Principles and Progress in the Global context

The objectives for innovation management listed earlier also need to be achieved within the global context. Design and choice of innovation model may also, therefore, need to take into account the issues raised in the discussion of Global Dynamics (page 6).

Conclusions

We have considered the question of "Who Owns Science" in the context of what we believe to be the purposes of science and innovation and evaluated the way in which ownership of science currently operates with respect to these purposes. It is clear that the dominant existing model of innovation, while serving some necessary purposes for the current operation of innovation, also impedes achievement of core scientific goals in a number of ways. In many cases it restricts access to scientific knowledge and products, thereby limiting the public benefits of science; it can restrict the flow of information, thereby inhibiting the progress of science; and it may hinder innovation through the costly and complicated nature of the system. Limited improvements may be achieved through modification of the current IP system, but consideration of alternative models is urgently required.

Responses

The Manchester Manifesto attracted considerable interest and comment, some supportive, some critical[2]. Here we review and respond to some of the more generic comments[3].

Criticism

Knowledge sharing is fundamental to the operation of the IP system.

iSEI Although publication is ultimately part of the patent system, the "climate of secrecy" it can promote is not one conducive to knowledge-sharing, in advance of patenting at least. The requirement for novelty discourages knowledge-sharing at the pre-filing stage. The expectation of patents means that many institutions have strict rules about publication and even talking to people; for example, the University of Manchester's own guidance advises: 'If you think your invention is potentially patentable it is essential that the details of the invention are kept secret until the application for the patent is made.' This is clearly against the sharing of information that would otherwise occur as part of the scientific process.

Post-patent, even automatic publication does not guarantee usable access to the information. Although the data may nominally be available once published through the patent system, we believe that data from these sources is often incomplete and needs an expert to decipher it. It would be useful, in fact, to know the average value of such data compared with other forms of publication; and this is part of the challenge issued by the Manchester Manifesto.

Criticism

Compulsory licensing provisions in patent rules mean that it is not possible to use patents to obstruct products from reaching markets.

iSEI In practice, fears of sanctions mean that compulsory licenses are rarely used, and the effect of the system is still to deny access to products to those who need them (t'Hoen, 2009; Odell-West, 2009).

Criticism

Patenting provides financial benefits to universities. Their research is not restricted because patent rules provide for experimental use exemptions.

iSEI This may be true in theory but it is not always or even often the case in practice. Because universities are being pushed to do more commercial or pre-commercial work, it is often unclear whether the research exemption will apply; the threat of an infringement action itself, even if ultimately unfounded, may deter research. Moreover the experimental use exemption in some jurisdictions is very narrow – this affects the global research climate.

For most universities the returns from patenting are very modest, and don't cover the full opportunity costs that they incur. Whether or not that is the case, our point is that such returns should be foregone in the public interest.

Criticism

Some say that IP blocks access to essential medicines, but investment in research and development for these drugs would collapse without it.

iSEI The Manchester Manifesto recognises that IP currently plays an important role in the financing of R&D, and that since this system is international no one actor can unilaterally alter it. All the more reason, then, to look critically at the system as a whole and to ask whether it is functioning optimally. Whilst politics and economics may be the driving forces that block access to drugs and prevent participation in innovation, IP law provides the tools that enable this to happen. Without these, politics would not be nearly so effective at denying ARVs to African populations, or at denying access to knowledge to developing countries. Of course this can be done by other means as well, but that is no reason to provide the tools and even encourage their use to perpetrate injustice.

There are two different issues at stake here – first, affordability of existing innovation; second, incentives for further innovation. The IP system is a tool for encouraging innovation for drugs for rich markets, but this mechanism does nothing about affordability, leading to the problems of access described. In the absence of a rich market, the IP tool is of no help in creating incentives to discover and manufacture drugs, leading to the problem of neglected diseases for which the "necessary investment to discover and manufacture" drugs is lacking. Both mechanisms to increase affordability, such as patent pools, and alternative incentives for innovation, such as prize funds, are needed to address these problems.

Notes

1. For the list of signatories see page 7 of the Manchester Manifesto, http://www.isei.manchester.ac.uk/TheManchesterManifesto.pdf.
2. Critical responses include: Prowse, P. (2009) *Patent profession welcomes Manchester Manifesto on science but slams 'misleading' comments on IP*, Chartered Institute of Patent Attorneys, available from http://www.cipa.org.uk/pages/press/article?D5C2CBED-894B-488B-ACD2-07B01E204A06 [accessed November 2010]; Worstall, T. (2009) 'Who owns Science? Manchester Manifesto can't answer', *The Register*, 4 December, available from http://www.theregister.co.uk/2009/12/04/manchester_manifesto/ [accessed November 2010]; Wild, J. (2009) 'The Manchester Manifesto and the IP world's failure to communicate', *Intellectual Asset Management Magazine*, 30 November , available from http://www.iam-magazine.com/ctredir.ashz?g=591e8d58-0f0c-40d8 [accessed November 2010]; and Brice, P. (2009) 'Who Owns Science: questionable critique of IP system', PHG Foundation News Story, 17 December, available from http://www.phgfoundation.org/news/5086/ [accessed November 2010].
3. See also: Harris, J., Chan, S., and Sulston J. (last updated 25 May 2010) 'Responses', available from http://www.isei.manchester.ac.uk/themanchestermanifesto/responses/ [accessed December 2010]; and Sulston, J., Chan, S. and Harris, J. (2009) 'How science is shackled by intellectual property', *The Guardian*, 26th November.
4. For a recent summary of this case so far see: American Civil Liberties Union (2010) 'ACLU challenges patents on breast cancer genets: BRCA', 30 October, available from http://www.aclu.org/free-speech-womens-rights/aclu-challenges-patents-breast-cancer-genes-0 [accessed November 2010].
5. The United States law appears likely to change on this point as a result of reconsideration of gene patenting following the recent District Court ruling that the BRCA1 and BRCA2 gene patents are invalid. The US Department of Justice has submitted an Amicus Brief to the US Court of Appeals in this case (No.2010-1406) stating that: "The district court's judgement in this case, however, prompted the United States to re-evaluate the relationship between such patents and the settled principle under Supreme Court precedent that the patent laws do not extend to products of nature. For the reasons below, the United States has concluded that isolated but otherwise unaltered genomic DNA is not patent-eligible subject matter." (US Department of Justice (2010) *Brief for the United States as Amicus Curiae in Support of Neither Party*, 29 October, available from http://www.genomicslawreport.com/wp-content/uploads/2010/11/Myriad-Amicus-Brief-US-DOJ.pdf [accessed November 2010]).

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Jensen, K. and Murray, F. (2005) 'Intellectual property landscape of the human genome', Science, 310, 5746, pp. 239-240.

Odell-West, A. (2009) 'The legacy of Myriad for gene-based diagnostics: a new policy and regulatory option', Journal of Intellectual Property Law and Practice, 4, pp.267-277.

t'Hoen, E.F.M. (2009) *The Global Politics of Pharmaceutical Monopoly Power*, AMB, Diemen, The Netherlands.