Introduction

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The chapters in this part discuss the wider social context in which scientists and industry create and distribute innovation. They explore policy options for intellectual property rights (IPRs) selected by public institutions and governments to manage innovation in biotechnology at institutional, national and international levels and the economic, social and ethical goals of IPRs as a component of innovation governance. The chapters consider whether the stated goals are being met, using empirical evidence, where possible, and potential IPR policy formulations that may maximize economic and social benefits flowing from biotechnology innovation.

Public opinion, our ability to regulate the use of technology and other concerns all play a role in shaping what innovation occurs and how it is introduced. Tim Caulfield's chapter analyses the problems surrounding public trust both in biotechnology research and in the products of biotechnology. Maintaining public trust is crucial for any kind of research, especially biomedical research, because of the need for dedicated public funds over the long term. Rightly or wrongly, biotechnology patents have become a flashpoint for the public as well as being the focus of policy debates as a proxy for more general concerns about commercialization of biomedical research. If we probe this generalized public angst around commodification of biomedical research, public survey data suggest that people are concerned about patenting life and the issue of access to technologies. There is a plethora of evidence that public trust in biomedical research is very fragile and that the research is carried out without taking into consideration the public's interests and values.

There are significant issues around the credibility of researchers and policy makers/politicians in the field of biotechnology. Publicly funded scientists are considered credible sources of information while industry researchers and publicly funded researchers who receive private funding are not. What is needed are governance structures for commercialization of biomedical research that maintain or enhance public trust. Caulfield suggests that patent pools may be one such governance structure. The benefits of patent pooling are risk spreading, decrease in transaction costs, and increase in investment possibilities. The criticisms are that it takes

away incentives, increases monopoly control, and may be difficult to negotiate, especially in academic publicly funded research. If patent pools are structured so that they have an independent governance scheme, however, they may address the public's concerns about commodification, conflicts of interest and trust in the independence of the research community.

The chapter by Jasper Bovenberg focuses on the accessibility of biological data. The study of common complex disorders requires links to be made between genotype and phenotype; between abstract genomic data and concrete patient medical records. This, in turn, requires that these data be made accessible to those who were not necessarily the primary producers of the data. There is a spectrum of accessibility to genomic and phenotypic data from large-scale collections of abstract genomic data produced by publicly funded scientists (for example, the Human Genome Project) to small-scale collections of phenotype data collected by individual scientists, typically in a hybrid clinical/research setting. These collections tend to be only conditionally accessible, as the primary producers often feel that they have earned an exclusive right to use 'their' collection.

Two unrelated developments may impact on the degree of accessibility of these data. First, large-scale projects are moving from assembling raw genomic data with little or no 'utility' in the patent sense, to producing 'functional data' with increasing utility. The increased 'patentability' of these novel data may undermine the data release policies of these projects. Second, data in the small-scale collections are increasingly being assembled by the research participants themselves. Consequently, traditional proprietary claims by individual researchers may come under pressure from claims by research participants.

The model of the Human Genome Project, where data are governed by the Bermuda Principles, is based on an ethos of academic sharing of research results and publication related data may be more broadly applicable. The Project's ethos is reinforced by the prospect of reciprocity. There is a failure to address the problem of free-riding by other scientists and commercial researchers, however, which may be addressed, in part, through creative licensing provisions. In addition, the model may not translate well to the increasingly prevalent participation of patient groups as key players in the promotion, facilitation and acceleration of studies of the causal role of genetics in diseases. These groups create and maintain databases with epidemiological, medical and other information about the relevant families, and biomedical researchers have become heavily dependent on the long-term participation and co-operation of cell and tissue donors.

A strong case may now be made that the active participation and substantive contributions of tissue/cell donors justify the retention of title to

the amassed collection. Bovenberg argues that the European database right could serve as a model. While traditional IP plays no role as regards the protection of collections of data, the recognition of a database right in large-scale collections of abstract (post-)genomic data could provide a meaningful remedy. It would be enforceable against all users who misappropriate or threaten to restrict the use to be made by others of the data collection, protecting the interests of researchers and patient groups who have invested substantial resources in the collection of valuable data and deserve a meaningful and enforceable positive right to exploit or control the collection.

The chapter by Sachin Chaturvedi addresses emerging trends in patent regime associated with agricultural biotechnology in developing countries. Plant variety protection (PVP) and patents have emerged as two important forms of IPRs. Both patents and PVP provide exclusive monopoly rights over a creation for commercial purposes for a limited period of time. Though the criteria for a patent are defined as novelty, inventiveness (non-obviousness), utility and reproducibility, along with provisions for compulsory licenses (CL), patent offices now grant biotechnology patents on microorganisms and, in some countries, on all life forms with no provisions for CL. In contrast, the intellectual property regime for plant variety protection emerged with a strong commitment to the public interest, including provision for CL.

Plant variety protection has worked well as a mechanism to promote the interests of plant breeders for developing new varieties through giving them proprietary rights, on the one hand, and treating plant breeders as custodians of public rights of access and use of genetic material, on the other hand. PVP encourages cross-licensing between a holder of plant variety rights (PVR) and a holder of a patent. Under the breeders' exemption of plant variety rights anyone may use protected material for breeding purposes. The patent regime does not reciprocate. In the patent regime the interpretation of research exemption is much narrower than that of the breeders' exemption in PVR. Unfortunately, the number of utility patents issued has grown very rapidly in the US. By December 1994, 324 utility patents had been issued for new plants or plant parts and 38 were issued for animals. As with Plant Variety Protection Certificates, most utility patents were awarded to the private sector.

The experience of the Indian seed industry, measured by the Research and Information System for developing Countries Seed Industry Study, shows the following results: (1) indigenous seed firms in India find it difficult to access relevant genes for development of new varieties in their biotechnological research as their sequence has already been patented by just one trans national company; (2) introduction of Bt (*Bacillus thuringiensis*)

characteristic without license even in other plants is completely impossible; (3) license fees are not regulated, are arbitrary and are incredibly expensive, and (4) consolidation of the industry is driving out smaller firms.

The discussion of these chapters focused on the presentations of Caulfield and Bovenberg at the workshop in Florence. There was a general consensus that patent pools, especially those with an independent governance structure, would be a useful mechanism for improving public perceptions of biotechnology. This may be further facilitated if patent pools are first established in areas of biotechnology perceived as having high social value, such as forest biotechnology and the preservation of heritage trees.

In Europe, however, it may be difficult to separate public concerns over GMOs *per se* and biotechnology patenting. Some examples highlight the distinction. There was general public outrage when Monsanto attempted to patent terminator technology and this played out in the media as a patenting issue. Ironically, however, self-help strategies such as terminator technology and trade secrets are chosen by innovators when patent protection is weak and there is a fear that patents will not be enforced.

It is also interesting that the profit motive is so distrusted by the public when many studies have indicated that other motivations have a much greater effect on scientific research, for example, self-aggrandizement and the building of large institutions. It seems strange that the public mistrusts a private biotechnology company with \$100,000 in assets but trusts a multi-billion dollar institution such as Harvard that styles itself as a not-for-profit educational foundation. The Walsh study found that individual desire to move forward academically had a more profound impact on data sharing than patents. Patents were not a significant factor in non-disclosure and the largest factor was career advancement. Other studies have shown race and gender effects.

Bovenberg suggested that without access to data there could be no scientific revolutions. This was explored from a historic perspective. Did this statement come from a view of the past where there was open access to data between members of the scientific research community that in fact never existed? From a historical perspective, there was a massive growth in mathematical science, chemistry and mechanics and the patent system/property rights from 1870–1914. At that point there were few mechanisms for technology transfer. In this respect, the illustration of patents and Watt's invention of the steam engine is actually more interesting from the perspective of what was not patented. Watt did not patent the efficiency measuring mechanisms he had in his works. Instead, he kept them a trade secret because they enabled him to gauge and understand what he was doing. It is likely that if the steam gauge had been made public, it would have done most of the work of diffusing the invention rather than stifling

it for, some people argue, as long as 31 years. Thus, the issue about how technology moves forward is not simply about patenting but also the access or non-access to the means that allow evaluation of the technology or science.

From an economic perspective, the term during which an invention is useful is the important subplot in innovation because the useful life of an invention is shorter and shorter. In many industries, valuation is not possible for longer than five years of market value because the discount rate drops to nil. Thus, patent duration is of decreasing importance. The question of who should own academic data collections has many alternative answers including the public, scientists, funding agencies, government, research projects and institutions. Problems may arise when these different actors have different rules and cultures around managing IPRs. The better question may be – Should anyone own it? – It may be better to set up a system of attribution through meta-tagging. One could argue that authorship is a way of ensuring both attribution and certification. Communities could develop standards such that the meta-tagging would be accommodated within protocols for communication of data.

At our workshop in Florence, it occurred to us that as we discussed the papers that were presented in session, the discussion had moved subtly from the issue of IPRs in innovation to their role in commercialization. To a lessening extent IPRs were viewed as an incentive for innovation, but IPRs were seen as a facilitator for the movement of information from place to place. Viewed in this way, the question to be faced is the extent to which patents are necessary to move from innovation to commercialization, and to what extent there are non-IPR dependent methods yet to be explored.

The central question is the compatibility of patent and non-patent systems for different forms of information. Do patents overwhelm other methods once they are introduced? In terms of the question asked at this workshop – What is the role of IPRs in innovation? — the answer is likely that IPRs do not have much of a role at the inventive stage. At the same time, it is evident that once value is added to an invention, patents have a significant role in creating and limiting social access to innovation. How we tie this well-known phenomenon to the impact of IPRs on commercialization is an area in which future research ought to be conducted.

That said, in the business context, patents protect investment. The private sector does not want to bring out a product that can be easily imitated. Industry pushes for innovation that it can take to the market, and patenting is the mechanism that gives assurance for that investment. From this standpoint, we could argue that if patents do not encourage business-driven innovation, they certainly play a necessary facilitating

role. Other forms or areas where society wants innovation are a separate issue – patenting is helpful for commercializing ideas, and at that level they spur innovation. There may therefore be a distinction in the role of patents in industry versus public science. In the private sector, patents play a role in providing a conduit for information to move into a commercial setting. Patents may provide an incentive to industry to move information around. Do patents have a negative effect on distributing other forms of knowledge, are these systems in parallel, do they conflict, or is there any relationship at all?