Several kinds of 'should:' the ethics of open source in life sciences innovation[*]

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What is the matter? Has Protagoras robbed you of anything? Yes, indeed he has, Socrates, of the wisdom which he keeps from me. But, surely … if you give him money, and make friends with him, he will make you as wise as he is himself.[1]

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[1] Plato, *Protagoras* (translated Benjamin Jowett, at 310d).

1. A sui generis ethical space for life sciences innovation?

Life science innovators work in an ethical space that is distinct from the general run of technology, whether or not they would choose this status. We expect life science innovation to serve such fundamental human needs as health, nutrition and environmental protection, and to deliver its fruits in the forms of proven and effective technologies as widely and equitably as possible. The call for access to the fruits of this innovation is more insistent than for any other technology, because essential human wellbeing – even life itself – is at stake; because a good proportion of the upstream inputs to applied life sciences research are derived from the public sector or from research funded by public or philanthropic sources; and because genetic inputs to research – biodiversity, human tissue, seeds – pose *sui generis* ethical and legal questions. Society's scrutiny over life sciences innovation is therefore more stringent and vigorously debated than is the regular run of technology, a scrutiny expressed at the ethical, political and formal regulatory levels.

It follows that in the life sciences especially, intellectual property (IP) law and its practice are typically viewed, from an ethical point of view, as essentially utilitarian means towards public policy ends, with their worth assessed from a consequentialist and empirical perspective. The attainment of 'justice' and 'equity' is measured in hard outcomes, and any appeal to 'natural law' underpinnings of IP rights or an inherent sense of entitlement is given an unsympathetic hearing in the busily contested policy arenas of life sciences. Ultimately, in this debate, only public policy outcomes count: the production and effective dissemination of certain concrete public goods. The IP system in the life science is expected to yield knowledge goods that are practically available as proven products and processes (new drugs, crops or uses of biodiversity), and higher level public goods,[2] such as global equity in distribution of these products, and ultimately equity in the enjoyment of the right to life[3] and in adequate health services. Given the strong emphasis on actual access to technologies and on tangible public welfare outcomes, the ethical framework is shaped essentially by the need to address the inherent scarcity of knowledge resources and research capacity (leading to neglected disease burdens and unmet

[2] For discussion of higher order public goods in this context, see Antony Taubman, 'Saving the Village: Conserving Jurisprudential Diversity in the International Protection of Traditional Knowledge', in Keith E. Maskus and Jerome H. Reichman (eds.), International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime, 521 (2005).

[3] In 2005, the adult mortality rate (probability per 100,000 of dying between 15 and 60 years) for women ranged from 789 in Zimbabwe to 45 in Japan; life expectancy for males at birth ranged from 39 (Angola) to 79 (several developed countries). (Source: World Health Organization, at www.who.int/healthinfo/statistics/en/).

agricultural needs), and to address inequities of access to research outputs; there is less said about the inherent sense of entitlement for the innovator and originator.[4] Where robust and credible incentives for private investment in research and development are recognized as being essential, this is nonetheless argued for broader utilitarian reasons and not because of any natural law entitlement. On the international policy plane, this turn to strong utilitarianism in evaluating the IP system is in part an unwitting consequence of the blending of trade policy and IP regulation though TRIPS. But there are special factors that further accentuate the hard utilitarian demands set for IP in the life sciences. The sense that much is at stake means that perceived failings and shortcomings in the system – any failure to innovate effectively, to address neglected needs, to ensure full and equitable access – attracts sceptical scrutiny and precipitates calls for reform and for new pathways for innovation in public health.

This search for alternatives to 'IP'[5] in life sciences innovation springs from a critique at three levels: (i) revisiting the inherent legitimacy of the foundational principles of IP law and policy; (ii) assessing how these principles are actually applied in practice at the level of governance and administration; and (iii) gauging the impact of the individual exercise of rights granted under the system. This critical analysis can, indeed, equivocate between these discrete levels, conflating the legal framework with the many and disparate distinct choices made within it. The broad legislative framework itself is critiqued from a hard consequentialist position: it is not assessed in terms of what it aspires to achieve, but in terms of its practical impact. But this critique can display a degree of ambivalence: if one were to accept the critique, *arguendo*, is the essential issue (i) the fact that exclusive rights over new technologies are available in principle under the law; or (ii) a practice of the administrators of the system granting actual patent rights that are inappropriately at odds with these principles, lacking the required attributes of true inventions; or (iii) the manner in which individuals and firms apply for, assert and deploy these rights when, in practice, this yields outcomes at odds with the policy goals of the system (using patents effectively to deny to the public the benefits of valuable new technologies or thwarting valuable innovation) or in tension with society's ethical

[4] But contrast traditional knowledge and associated genetic resources for which natural law claims are mingled with calls for historic retribution for misappropriation, and the invocation of higher order public goods in the form of conservation of diversity of biota, of cultures, of jurisprudence.

[5] In this polemical context, 'IP' is often conceived as a distinct innovation system and set of values, rather than – more accurately, in this writer's view – as a precise kind of legal mechanism that can be implemented in radically different ways to construct diverse innovation systems and to express and defend diverse value systems.

expectations (e.g. pushing the cost of a diagnostic test beyond the reach of all but the wealthy, or illegitimately profiting from others' investment in research)? Is the root problem raised in the debate the very system design, its broad execution, or individual choices that conflict with systemic goals? If a potential critique determines that the essential problem is a mix of all three, how can interventions be calibrated and applied so as to match practical remedies with each facet of the problem? The debate over 'open source' biotechnology is a fascinating case study as it can at times be phrased as a critique of the legitimacy of the formal grant of exclusive rights as such over critical technologies, but as a practical intervention it can seem to aim at reform of actual behaviour and actual choices in the deployment of such rights.[6] Could it reform the essential conception of what should be the legitimate bounds of an exclusive right, by influencing actual practice and the effective normative expectations upon right holders?

Precisely because so much is at stake – conceivably, the future wellbeing of humanity – it is proper for the same ethical and empirical rigour that is applied to the conventional IP system to be applied equally to proposals for the reform, renouncement or replacement of that system: assertion of new modes of innovation that are disruptive or divert resources merits the same ethical scrutiny as the complacent endorsement of the *status quo*. The current necessary, valuable, active debate about how best to optimize innovation processes in the life sciences: how best to draw in and structure the different inputs needed – finance and infrastructure, platform technologies, know-how, regulatory data or product development capacity – and how to ensure equitable dissemination of the fruits of innovation, cannot run the risk of privileging certain abstracted models over a robust and practical assessment of what actually functions, what will deliver.

A priori theoretical preferences range from viewing recognition of intangible property as a bedrock of a sound knowledge economy[7] and as a precondition for the transactions in intangible inputs that construct a new life sciences product, to

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[6] The contrast between a policy intervention and the encouragement of preferred forms of exercise of rights is captured well in the preamble of the GNU General Public License Version 3 (29 June 2007), at www.gnu.org/licenses/gpl-3.0.html: 'States should not allow patents to restrict development and use of software on general-purpose computers, but in those that do, we wish to avoid the special danger that patents applied to a free program could make it effectively proprietary. To prevent this, the GPL assures that patents cannot be used to render the program non-free.'

[7] See Alexandra C. Horst, International Property Rights Index (IPRI): 2007 Report, at www.InternationalPropertyRightsIndex.org: 'Once a domain mainly considered by the affected inventors and companies themselves, public interest in intellectual property protection has risen substantially, as the vast majority of the world is now affected by its success or failure' (at 8).

acute scepticism about *any* propertisation or legal exclusivities over knowledge goods in the life sciences.[8] Both sets of preferences are argued to be justified by a blend of strictly utilitarian and broader ethical and human rights arguments, often with some equivocation between the two: is public choice to be guided by what is right or by what works, is it right because it works, or does it have to be right (or legitimate) in order to be practically sustainable? In practice, an unexpectedly pluralist spectrum and a supple range of diverse innovation models stretch between these two extremes; while the conceptual dichotomy between the two fuels much debate, the actual working mechanisms that deliver beneficial products typically ply the extensive territory ('policy space') that lies between these two conceptual positions.

The present comment explores the ethical framework for analysing innovation structures in the life sciences to assist in the rational choice of model to support desired innovation and access outcomes, with a particular focus on the conceptual infrastructure for analysis of open source models in the life sciences. This search for rigour is, however, the precise opposite of a sceptical or reactionary appraisal: it is a strategy that aims to shift the search for new models and new structures from an academic inquiry and from an exchange of memes into a practical art: reduction to practice.

The call for open source innovation is at one level a reaction to the observation that the foundational choice in IP policymaking is, at first blush, radically counterintuitive; this is one reason why the patent system in general is subject to a repeated cycle of sceptical review: lawmakers provide for patents in order to induce the production of public knowledge goods, such as new technologies, that would not otherwise be financed and produced, and they do this by a means of structured, systematic exclusions from the public domain. In short, public goods are produced by restricting the public domain. IP management in the life sciences has to reconcile this superficial tension between the exercise of exclusive rights and the promotion of public welfare outcomes, and to ensure that the tension remains only superficial rather than structural: in principle, innovations are excluded from the public domain in order to garner the concentration of resources that is necessary to take an

[8] E.g. the recasting of intellectual property rights as 'intellectual monopoly privileges' (IMPs), see e.g. Greg Martin, Corinna Sorenson and Thomas Faunce, 'Balancing intellectual monopoly privileges and the need for essential medicines', 3 Global Health 4,. 2007 (Published online 2007 June 12. doi: 10.1186/1744–8603–3–4).

invention entirely through the production pipeline to yield a practically useful product.

In principle, therefore, a utilitarian, objective IP policymaker has to determine what privately-held exclusions from the public domain of otherwise non-excludable knowledge resources are required to harness sufficient private interest to provide for the production of useful public goods that would not otherwise come into existence.[9] But how does the objective policymaker, ideally removed from sectoral bias, in the original position behind a Rawlsian veil of ignorance,[10][10] determine what exclusions would be just; or legitimate; or effective; and what blend of hard utilitarianism and more abstract appeal to justice is right? And in setting these formal legal exclusions from the public domain, what assumptions are made about how individual actors will exercise the ensuing exclusive rights? Classical liberal economic analysis[11] (the 'invisible hand')[12] suggests that overall public welfare is unwittingly advanced by the cumulative effect of individual economic actors pursuing their private interests. But can such an analysis be reliably extended to the promotion of welfare through the production of intangible public goods generated by the recognition of private rights under the IP system? Some public goods would result either directly or as externalities from the pursuit of private interest, as the spontaneous ordering of the market and communication through market exchange promotes beneficial investment and innovation. Classically applied to goods and services,[13] this analysis may illuminate the harnessing of private interest to produce

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[9] This is not, of course, by any means the sole mechanism for harnessing private interest to provide for public goods. There is, for example, a considerable economic literature on the private provision of public goods, considering such phenomena as corporate philanthropy, political campaign donations. See Eduardo Ley, 'On the Private Provision of Public Goods:A Diagrammatic Exposition', 20 Investigaciones Economicas 1, 1996, 105–23, at IMF, Washington DC, http://econwpa.wustl.edu/eprints/pe/papers/9503/9503001.abs. See the economic model for non-cooperative provision of public goods in Theodore Bergstrom, Laurence Blume, and Hal Varian, 'Private Provision of Public Goods', 29 Journal of Public Economics, 1986 25–49. at http://econwpa.wustl.edu/eprints/pe/papers/9503/9503001.abs.

[10] John Rawls, A Theory of Justice, Harvard University Press, 1971; R.J. Kilcullen, Rawls: The Original Position, Macquarie University, 1996, www.humanities.mq.edu. au/Ockham/y64l13.html.

[11] For a brief historical review of these aspects of liberalism, see Steven Horwitz, 'From Smith to Menger to Hayek: Liberalism in the Spontaneous Order Tradition', 6 The Indep. Rev. 1, 2001), at 81.

[12] In Adam Smith's classic formulation: 'by directing that industry in such a manner as its produce may be of the greatest value, he intends only his own gain, and he is in this, as in many other cases, led by an invisible hand to promote an end which was no part of his intention. Nor is it always the worse for the society that it was no part of it. By pursuing his own interest, he frequently promotes that of the society more effectually than when he really intends to promote it.'

[13] With the assumption that intangible knowledge products are not economically significant: note Smith's reference to the intangible or ephemeral product of 'players, opera-singers, opera-dancers, etc.' as producing 'nothing which could afterwards purchase or procure an equal quantity of labour.

intangible knowledge products of benefit to society, offering a systematic utilitarian ethical basis to IP mechanisms. Intangible property, or exclusions from the public domain, can promote the spontaneous order that works for society's overall gain: accepting limitations on commercial use of knowledge through legally crafted exclusions may be the most effective way of producing some public goods.[14] But it would be politically naïve, ethically obtuse and analytically barren to rely wholly on this mechanism in a laissez-faire manner as the sole means of ensuring the production of public knowledge goods in the life sciences. Precisely tailored exclusions from the public domain are essential to capture and direct private interest towards the production of certain public goods that would otherwise not exist: for instance, this is the rationale, at least, of orphan drugs initiatives and some approaches to protection of test data for pharmaceuticals and agricultural chemicals. But the complexity of the pathway towards a finished product, the need for a broad base of infrastructure and openness of knowledge, and the distinctive risk patterns of life sciences innovation also entail an exceptional need for public impetus to research, public policy direction setting and distinct public financing of public goods[15] in such areas as health, agriculture and the environment. One line of argument against exclusive rights and their restrictive exercise is indeed the high level of public funding that goes into the innovation infrastructure and the key upstream technologies in these fields. Yet to relinquish altogether the possibility of exclusive rights over such public inputs, waiving any residual say over their application and the distribution of derivative benefits, is itself an expression of confidence in another invisible hand, one that draws enlightened private capital and public researchers together into welfare-enhancing partnerships that invest resources and opportunity cost into the development and delivery of products built from public domain inputs. In some circumstances, at least, the prudent policymaker will retain a reserve possibility of invoking 'private' rights to induce more socially beneficial applications of public-origin technology, and to exert leverage over downstream uses of this technology.

Like the declamation of the actor, the harangue of the orator, or the tune of the musician, the work of all of them perishes in the very instant of its production.' Smith A., *An Inquiry into The Nature and Causes of the Wealth of Nations*, Henry Frowde (ed.), Oxford Univ. Press, 1909, 1776.

[14] The imposition of an exclusion means that they cease to be true public goods, as these are by definition not excludable, but the disclosure requirements of technology-related IP protection are intended to ensure that protected subject matter passes into the public domain firstly as a public knowledge good (patent information is not, in principle, excludable from the time of its publication), and, through limited term.

[15] Samuelson, P. (1954), The Theory of Public Expenditure', **36** *Review of Economics and Statistics*, 386–9.

But much hinges on how those private rights are exercised, and by whom they are held: the mere formal recognition that a legal right exists to exclude third parties is only a small part of the overall pattern of knowledge management, since so much depends on who is excluded, and who is included, by those exclusive IP rights, and to what ends, and subject to what conditions. This is perhaps one broad systemic message of the open source paradigm as applied to the life sciences: 'It's not what you got, it's how you use it.'[16]

2. Analysing options for knowledge management in life sciences innovation

Indeed, actual patterns of life sciences innovation – the life cycles of real products – confute *a priori* assumptions of a fundamental choice between private or public good structures, or between the impetus of exclusive private rights or direct public interest. Actual patterns of ownership and control of patented technology illustrate how the grant and exercise of 'private' rights over IP subject matter need not be solely or even marginally directed towards private interest: it is increasingly inaccurate to conflate the private or exclusive nature of IP rights with the narrow pursuit of private interest. IP management that is solely and explicitly directed towards promoting public interest outcomes can include defensive publication and the pre-emptive creation of a public domain (including by waiving IP rights)[17], but it also includes the judicious deployment of legal exclusions. For instance, an IP-based right to exclude can encourage direct allocation of private resources towards public interest outcomes or leverage access to privately held background technologies for non-profit innovation, in the absence of market incentives.[18] Exclusive rights can be licensed to preclude commercial use of protected materials, to promote noncommercial creative exchange and adaptation.[19] In the life sciences, a right to

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[16] In this form, apparently written by Eddie Kendricks, 'It's Not What You Got' (single, Motown Records, 1976); but note also the consequentialist, outcome-oriented ethic in an earlier similar lyric: 'T'ain't what you do, it's the way that you do it… That's what gets results'. ('Tain't What You Do (It's The Way That You Do It))', James Young and Sy Oliver), Decca Records, 1939 (Ella Fitzgerald, vocals).

[17] See for example the public domain dedication of the Eldritch Press: 'Eric Eldred hereby releases any creative addition to the literary materials at the Eldritch Press including but not limited to any copyrightable compilation of materials or HTML formatting to the public domain with a Creative Commons Public Domain Dedication.' (at http:// creativecommons.org/licenses/publicdomain/eldred/).

[18] Taubman, A. *Practical Management of Public-Private Alliances for Public Health Outcomes in the Developing World: The Lessons of Access Conditions in Research and Development Agreements,* Initiative on Public-Private Partnerships for Health in Global Forum for Health Research, Geneva, 2004. www.ippph.org.

[19] See for example the 'Attribution-NonCommercial-ShareAlike 1.0' draft license at Creative Commons International (UK): 'You may not exercise any of the rights granted to You in Section 3 above in any manner that is primarily intended for or directed towards commercial advantage or monetary compensation.' (at http:// creativecommons.org/worldwide/uk/, last visited May 14, 2005).

exclude can be deployed to preserve open access to pre-competitive or upstream inputs to applied or downstream research. Thus the right to exclude can be applied judiciously to safeguard the open quality of a shared innovative domain for agricultural biotechnology (exercising exclusive IP rights to preclude third parties from excluding access to derivative outcomes).[20] In this context, the distinction between an 'open source property right' construed as a 'right to distribute' rather than 'a right to exclude'[21] – while perhaps useful and illuminating in a polemical context – cannot be maintained at a foundational or formal level: a 'right to distribute' is either unconditional and unbounded, in which case it is defined by the absence or waiver of the originator's right to exclude; or it is conditional[22] on certain behaviour (such as granting in turn similar rights to distribute) or undertakings, in which case the IP right is exercised to exclude other forms of distribution or other patterns of downstream use. Standards bodies use IP licensing structures to ensure open access to standards while encouraging technology developers to pool their technologies for mutual benefit, such as by defining fair, reasonable and non-discriminatory (FRAND) terms and conditions for licenses.[23] The claim for protection of traditional knowledge is expressed by some proponents, at least, as a collective right or custodial responsibility to prevent illegitimate use of this knowledge, entailing the exercise of rights to exclude third parties in the name of *a* public if not *the* public – i.e. the traditional community which maintains the

[20] See for example Biological Open Source License for Genetic Resources Indexing Technologies at www.bios.net/daisy/GRITLicense/750/1170.html.

[21] Weber S., *The Success of Open Source*, Harvard University Press, Cambridge, 2004.

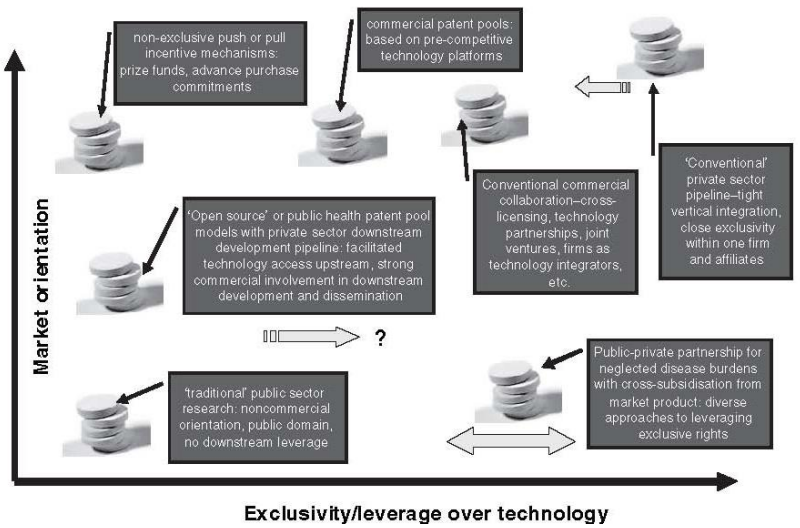
[22] See for example GNU General Public License (a free software, not open source license). The Preamble explains: '[t]o protect your rights, we need to prevent others from denying you these rights or asking you to surrender the rights. Therefore, you have certain responsibilities if you distribute copies of the software, or if you modify it: responsibilities to respect the freedom of others. For example, if you distribute copies of such a program, whether gratis or for a fee, you must pass on to the recipients the same freedoms that you received. You must make sure that they, too, receive or can get the source code. And you must show them these terms so they know their rights.' Paragraph 8 provides: 'You may not propagate or modify a covered work except as expressly provided under this License. Any attempt otherwise to propagate or modify it is void, and will automatically terminate your rights under this License.'

[23] Concerning the resolution of conflict between the exclusivity of IP rights and open access to standards in the United Kingdom, 'most standards bodies include procedures that take IPRs into account where a standard is in the process of being drawn up. Each participant is expected to declare at an early stage the IPRs it holds which are (or might be) essential to the draft standard if it were to be adopted. The owner is requested to give an undertaking in writing that it is prepared to grant irrevocable licences on royalty-free or fair, reasonable and non-discriminatory (FRAND) terms and conditions under such IPRs, with a waiver of copyright in documentary material. The standards body also makes sure that the patent in question is endorsed as a 'Licence of Right' at the Patent Office. This ensures that licences under the patent are available to all applicants as of right and that any disagreement of licensing terms is subject to settlement by the Patent Office,' Clarke M, *Standards and Intellectual Property Rights* (2004), at 64.

knowledge according to customary law and practice.[24] Public-sector knowledge management through the assertion of IP rights can be construed as a form of privatisation of public knowledge, or idealised as a means to maintain collective public-interest control over how public knowledge is developed and applied.

In practice, life sciences innovation practices and structures range across an unexpectedly pluralist spectrum and a supple range of options lying between conceptual extremes. Moving beyond the conventional antinomies of public/private and exclusivity/openness opens a stronger conceptual framework for analysing innovation structures in the life sciences, and in turn assists in the rational choice of model to support desired innovation and access outcomes. Actual development and effective delivery of life sciences products to a target public involve a diverse mix of public, private but part publicly funded, and strictly private inputs; and the cluster of diverse technological inputs that converges on a delivered life sciences output will be governed, licensed and made available in diverse manners. There is rarely a one-to-one correspondence between a patent, or a licensing model, or a genetic input, and an actual complex product such as a new seed or drug, which in its available and functional form will be a convergence of inputs: genetic material, know how, foreground inventions, platform technologies and test data. A hybrid mix of forms of knowledge management is therefore bound to be experienced: Figure 1 depicts how innovation structures make use of a range of options between fully

Figure 1 Modes of knowledge management in the life sciences



[24] See Taubman A.S., Saving the Village.

open access and exclusivity, on one axis, and between different levels of engagement with the market on the other. The knowledge management task for the product innovator – whether public or private, or both – boils down to determining what position on this landscape is likely to achieve the practical outcomes desired, recognising that at least some leverage over technology and some engagement with the market will likely be required.

Hence the utilitarian policymaker, operating behind an ethical veil of ignorance (with the aim of remaining disinterested and unbiased so as optimally to promote public welfare) and a technological veil of ignorance (confronted with radical unpredictability and high risk levels as to what research pathway will actually yield desired innovations, when and how), needs to consider how to navigate these options and how to encourage optimal behaviour on the part of innovators, assuming that the intense level of public interest will not, politically, accommodate a *laissez-faire* attitude on the part of those managing the innovation policy and legal framework. Yet *a priori* assumptions about the value of specific models are unlikely to do justice to the complex assemblage of inputs that yield the desired outcome.

3. Free (*libre*) and open source as a model for life sciences innovation

The call for open source innovation in the life sciences, by analogy with free (*libre*) or open source software (OSFS), is a striking topical example of the ethical ambivalence that can attach to specific models of knowledge management. 'Open source' is used here as a provisional bookmark for a cluster of conceptually linked innovation structures:[25] in Figure 1, the open source model lies towards the left-hand side, ranging up and down the axis of market orientations, as it accepts that a market for derivative products may be a legitimate means of generating the resources and the pathways to bring useful products to the market. It is also a model that entails some limited use of a right to exclude: specifically, the exclusion of those who seek in turn to exclude. But what kind of ethical and prudential guidance might determine the choice of such a mechanism, and determine the specific choice of mechanism within the cluster of possibilities?

[25] The much discussed and conceptually non-trivial distinction between 'open source' and 'free' software is not addressed here, not because it isn't important, but because this paper raises questions that would precede a close discussion of such distinctions in either software or the life sciences. The term open source or free software (OSFS) is therefore used henceforth to refer in general to this cluster of modes of software development.

It's wisest to acknowledge that mixed policy rationales are put forward to argue for an open source approach to life sciences: there is no one ethical argument that holds sway. At times, the rationale can veer towards the logically circular, or at least pose a question-begging justification: a life sciences innovation model may be useful, ethically progressive and worth exploring for the public good, but is it open source enough to earn that epithet? Indeed, given the cultural and social appeal of the open source concept and the somewhat loose invocation of these terms, a valuable – occasionally heated – debate is conducted over what might be termed 'identity preservation' of various forms of OSFS, given the risk that a potent set of ideas and norms can be reduced to a form of social branding, rather than as a significant and distinctive form of innovation structure. On the other hand, there may be features of OSFS software, such as the freedom to 'fork the code'[26] that may be considered essential to a credible migration of the open source meme to the life sciences domain.[27] Yet the objective differences between software coding and breeding plants and formulating medicines – the distinct modes of innovation, of risk and liability management, of identifying a 'kernel' or a 'commons', of regulating and testing technologies – can lead practitioners to challenge 'expectations that one size fits all'.[28] In practice, proponents and analysts of open source models do need to operate at several analytical levels, and the call for open source R&D in the life sciences can be framed variously as:

- a meme – a unit of social evolution[29] – or as a distinct complex or system of memes (a memeplex), conceiving open source as a cultural community,[30] as an evolving innovative culture shaped by certain cultural norms (such as willingness to share improvements);
- a metaphor – the notion of open source in software development offering a general pattern for structuring networks of life sciences researchers, for

[26] See, for example, the discussion of the BiOS licence in Hope, J., 'Open Source Genetics: A Conceptual Framework', Chapter 12, in van Overwalle, G. (ed), Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes, Cambridge, 2009.

[27] As Hope remarks (*op. cit.*) this kind of analysis should be 'not mere pedantry, but a question of institutional design.'

[28] Berthels, N. and Jefferson, R., 'Case 8. CAMBIA's Biological Open Source Initiative (BiOS)', Chapter 13, in van Overwalle, G. (ed), Gene Patents and Collaborative Licensing ModelsPatent Pools, Clearinghouses, Open Source Models and Liability Regimes, Cambridge, 2009.

[29] A 'unit of cultural transmission, or a unit of imitation': Richard Dawkins, *The Selfi sh Gene*, 1976.

[30] Levy S., *Hackers: Heroes of the computer revolution*, New York, 2001, commenting on the sense of the loss of a community that triggered the free software movement.

instance considering access to nucleotide or peptide sequence data as equivalent to free access to source code,[31] and so on;

- more formally, a model or template – open source licensing structures or similar contractual mechanisms granting access on the condition of reciprocal access applied *mutatis mutandis* to life sciences research and development;
- a badge of ethical approval – affirming an inherent ethical value in open source behaviour.

Its attractive brand presence could lead to 'open source' being loosely applied to any kind of life sciences innovation one happens to prefer, provided it falls short of the exclusive exercise of intangible property rights: a badge of approval or commendation for deciding not to exercise rights exclusively. Hence the ethical basis for such advocacy may range from the strictly utilitarian – it just works better – to something approaching an aesthetic of innovation – 'open source' as a kind of hip/ geek T-shirt slogan.[32] The open source model could become an end in itself, acquiring an intrinsic ethical or even aesthetic validation. But without denying its social or cultural component, surely the policy rationale for OSFS development is more compelling when phrased in strictly utilitarian terms: it is ultimately 'better' and worth advocating as a mode of innovation when and if it works better for its ostensible objectives, more so than when we approve of it or when it conforms with an abstract model. This suggests that the open source concept would be more productively employed as an *heuristic* for innovation policymakers; advocacy of consciously disruptive models in the life sciences would evolve into a program of harvesting empirical lessons from successful forms of collaborative innovation in the software domain, with a focus on how to make life sciences innovation work better, work more efficiently, and/or work more fairly (in short, 'from concepts to cases').

In describing the practical, heuristic character of open source innovation, for instance, the BiOS FAQ expands: 'people don't just provide solutions; they provide an understanding of how the solution was developed and a way that the solution can be modified to suit other people's needs, and used to develop products. In

[31] See The Open Source Definition (Annotated), Version 1.9 (July 24 2006), at www.opensource.org/docs/definition.php.

[32] An analogy may be drawn with the assertion of Creative Commons licences in good faith but for social branding purposes technically at odds with the actual content concerned – which in the author's experience has included Creative Commons licences over fully public domain patent documentation (entailing the effective assertion of copyright) and over text ('available for widescale, free, non-commercial reproduction') protected by technological protection measures through a paid-for password (on file with the author).

reality, the concept of open source applies to anything that requires a meeting of innovative minds.' This analysis could be equally applied at a broader level to transferring 'understanding how the solution was developed' from one sector of innovation to another. Yet the essential conundrum remains: how to avoid the constraints of a 'naïve expectation that one size fits all',[33] while porting coherent and useful lessons that are 'sector agnostic' to the aid of socially beneficial life sciences research? It is submitted that the preferred analysis should be pragmatic – guided by the practicalities of constructing a functional innovation platform for a given field of technology, and assessed ultimately according to its utilitarian impact.

In establishing an ethical framework for open source in the life sciences, a key consideration, with bioethics and broader utilitarian aspects, has been where to draw the line between the information that should remain freely available (subject to privacy and other ethical concerns from the point of view of the providers or subjects of especially human genetic data)[34], and what should be considered legitimately 'proprietary': what is the upstream material that goes into the pool, and what is a legitimate derivative product that (i) can, ethically, be commercialised by one firm exclusively and (ii) should, pragmatically, be open to exclusive appropriation by a firm as the most effective form of engaging market incentives to bring a downstream product to the public. These broader ethical and more narrow utilitarian considerations converge when the judgement is made that genetic information should intrinsically be considered in the public domain, because of fundamental ethical considerations but also because of the pragmatic assessment that such information should be considered 'pre-competitive' – in other words, ethical and utilitarian concerns led to the view that the provision of raw genetic data shouldn't be a business model in itself. The SNP Consortium, which was formed and funded by major private and public actors in 1999, subsequently delivered some 1.8 million single nucleotide polymorphisms (SNPs) into the public domain.[35] [35] The utilitarian rationale for this pre-competitive collaboration was expressed in utilitarian terms:

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[33] Berthels, N. and Jefferson, R., 'Case 8. CAMBIA's Biological Open Source Initiative (BiOS)', Chapter 13 in van Overwalle, G. (ed), Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes, Cambridge, 2009, n. 28.

[34] The fact that genomic epidemiological research is so far upstream in the pipeline of therapy development has implications for the privacy rights of research participants and for a rigorous definition for prior consent, particularly in resource-poor settings.' (Chokshi D and Kwiatkowski D, 'Ethical Challenges of Genomic Epidemiology in Developing Countries', **1** *Genomics, Society and Policy,* 2005, 1.)

[35] Now accessible at www.ncbi.nlm.nih.gov/SNP/.

The members of The SNP Consortium will be able to create a commonly accepted SNP map more quickly, and with shared financial risk and less duplication of effort than if each company proceeded on its own … the map that will be constructed will be of greater density and therefore potentially greater utility to the pharmaceutical industry than SNP maps currently available.[36]

But competition and the assertion of patent rights were considered legitimate, indeed desirable, for downstream innovations derived from the open SNP data,[37] as a means of delivering useful finished products to the public, building on the pre-competitive substrate. The SNP Consortium itself filed patent applications and obtained a defensive registration as means of leveraging continued open access.[38]

Yet too strict a consequentialist account may end up placing excessive emphasis on short-term outcomes, overlooking the value of investing in technology platforms and information tools such as the SNP map. The SNP map could not of course yield useful medical products in itself and has contributed, for instance, to the International HapMap Project,[39] identifying haplotypes and enabling association studies, which 'will benefit human health by providing an extensive resource that researchers can use to discover the genetic variants involved in disease and individual responses to therapeutic agents. Once such variants have been discovered, researchers can learn much more about the origins of illnesses and about ways to prevent, diagnose, and treat those illnesses,' thus contributing further to a common platform for the ultimate delivery of new treatments, but still an interim step with its utility to be assessed in such terms.

Hence, given the long lead-times, progressive construction of technology platforms, and complex integration of diverse inputs required to yield new life sciences inputs – as well as a healthy experimental need for trial and error – a utilitarian argument may also be made for interventions that open up new pathways and structures for innovation as ends in themselves, even before tangible products are yielded.

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[36] 'Frequently Asked Questions,' The SNP Consortium, at http://snp.cshl.org/about/faq.shtml, last visited 13 March 2005.

[37] Chokshi D and Kwiatkowski D, at 8.

[38] US patent applications 20060057564, 20030204075 and 20020198371 (all abandoned as applications before grant), and statutory invention registration (SIR) H2,191, June 5, 2007 held by SNP Consortium (the SIR is a registration which 'has the defensive attributes of a patent but does not have the enforceable attributes of a patent', 35 U.S.C. 157)

[39] The International HapMap Consortium, 'The International HapMap Project,' **426** *Nature*, 18 December 2003, 789.

It is inherently improbable that any broadly defined mechanism is likely to serve as the optimal, exclusive pathway for all innovation processes within any sector of life sciences, and the invocation of alternative pathways increases the need for a clear framework for assessing these options and for constructing appropriate forms of regulatory intervention to optimize the welfare impact of life sciences research and development. Equally, however, invoking new models for innovation may divert attention towards a relatively abstract discussion about models, and away from fundamental technical obstacles to creating beneficial new products: the view of open source as 'magic pixie dust',[40] that it will in itself yield solutions. When transferring the OSFS meme to life sciences, a key stumbling block is that of false analogising: biotechnology differs fundamentally from software development in key ways, discussed below. Yet several factors may predispose the analyst to a stronger ethical basis for 'open' models in the life sciences than in software: it concerns basic human needs and welfare; public funds account for a significant proportion of research; there are stronger ethical, safety, and environmental concerns, as well as more acute ethical concerns about the obtaining and exercise of *patenting* technology in this domain, including also the cluster of issues concerning equity and prior informed consent for genetic inputs to research, which broaden into a North-South political and trade debate. And there is only one operating system; one can't invent around DNA chemistry nor develop a functional alternative to a gene.

The underlying question, then, is whether 'open source' is a coherent and enabling concept for biotech innovation: is it a badge of approval for behaviour we like, or can the experience of open source software development act as a heuristic for the construction, analysis or retrospective validation of distinct forms of research and development in the life sciences? And if 'open source' or 'free' life sciences innovation can be coherently characterised as a distinct mode, is the rationale for pursuing this mode one of inherent self-interest (it works for the innovator) or a moral duty (it works for society)?

More generally, how to characterise the inducement or the obligation to pursue open source innovation, drawing on the experience (or culture) of open source software development? Some common themes emerge: the notion of collaborative but distributive fashioning of technological platforms for downstream innovation; the contrast between source code and finished products, and between the free use of pre-competitive information and a competitive market for derivative products; an ethic of distributive equity in the share of derivative benefits and resistance to

[40] Zawinski J, *Resignation and Postmortem*, 1999 jwz@jwz.org.

exclusive appropriation of benefits from platform technologies; the goal of freedom to use or operate as against tight structures of vertical or horizontal technological integration, backed by ethical expectations of freedom to use or experiment; and the use of viral licensing techniques to sustain freedoms in derivatives or applications of core technology. In both spheres, the model is driven partly by a meme of a golden age of technological freedom (whether it is open software development, or free exchange of genetic materials such as seeds), contrasted with the rise of the dominant industry behemoth (software giants, seed multinationals), and the appeal to bridge a technological divide (digital or biotechnological), and to democratise the innovation process. In both spheres, too, the boundary between technology user and innovator blurs – what Lessig construes as 'read-write culture'.[41] But, crucially, in each case the open or free innovation structure is technology driven – the rights associated with a 'core' or original or 'platform' technology are asserted to leverage continuing access to derivative uses or adaptations of that technology, which itself is progressively improved. Ultimately, the most robust and persuasive inducement to enter the open source structure will be nothing more abstract than access to useful technology.

Important contrasts between these two fields suggest caution in too immediate an appeal to an OSFS model for the life sciences. First, the research and development dynamic is objectively different, as is the economic and commercial background. And the structure of liability, social responsibility and public interest regulation differ dramatically: 'viral dissemination', 'bug fixing' and the 'blue screen of death'[42] take on dramatic import in the life sciences. A buggy first version of Linux can be benignly released to the hacker community's bazaar[43] for Linus's law[44] to do its therapeutic

[41] Lessig, The Read-Write Society, Keynote Address, Wizards of OS4, 15 September 2006, at http://wizards-of-os.org/index.php?id=2322

[42] http://bsods.com/.

[43] In the cathedral-builder view of programming, bugs and development problems are tricky, insidious, deep phenomena. It takes months of scrutiny by a dedicated few to develop confidence that you've winkled them all out. Thus the long release intervals, and the inevitable disappointment when long-awaited releases are not perfect. In the bazaar view, on the other hand, you assume that bugs are generally shallow phenomena – or, at least, that they turn shallow pretty quickly when exposed to a thousand eager co-developers pounding on every single new release. Accordingly you release often in order to get more corrections, and as a beneficial side effect you have less to lose if an occasional botch gets out the door.' ('Release Early, Release Often' in Raymond E., *The Cathedral and the Bazaar*, Thyrsus Enterprises, <thyrsus.com>, version 3.0 (2000)).

[44] 'Linus [Torvalds] was directly aiming to maximize the number of person-hours thrown at debugging and development, even at the possible cost of instability in the code and user-base burnout if any serious bug proved intractable. Linus was behaving as though he believed something like this: Given a large enough beta-tester and co-developer base, almost every problem will be characterised quickly and the fix obvious to someone. Or, less formally, 'Given enough eyeballs, all bugs are shallow.' I dub

work on the code, but the release of a buggy open source vaccine or drug could yield a public health crisis: in life sciences innovation, there is often little clear distinction between management of IP and management of liability. The kind of broad disclaimers typically found in software licensing (open source, free or otherwise) could not be sustained for much life sciences innovation.

If open source licensing indeed pivots on a 'right to distribute',[45] public health and environmental regulation – and diffidence about 'viral dissemination' not only of licensing structures but also of public liability – may inhibit free use and dissemination of life sciences technologies exactly as they close in on offering tangible public welfare – as usable products in the hands of the public. A true 'open source' approach to life sciences innovation may need to address the contentious question of what competitive relationship should exist between the originators and users of test data (such as clinical trial data); a hard open source reading may entail access to competitors' full regulatory dossiers by analogy with 'derived works';[46] as a product moves from the lab bench to the dispensary, the open source design would need to make choices on the economics of clinical trials, not merely proof of concept. It would have to address, too, another distinctive characteristic of life sciences innovation today: the claim for actual property rights or quasi-property rights over non-inventive inputs into the research, in the form of genetic material, or what Kloppenburg termed 'a form of national property'.[47] In short, if the value of the model is to be assessed from a complex ethical framework that links the need to accommodate interests and equities reaches further upstream and downstream than the software model.

Without overplaying such resonances, IP law and practice already offers several tools that could be deployed in open source or free life sciences innovation structures. Past examples exist of the open dissemination of research tools through non-exclusive, accessible licensing; of cross-licensing structures that maintain collective access to improvements; of collective undertakings to maintain free access to genomic information as a 'pre-competitive' foundation for derivative innovation.

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this: 'Linus's Law'' (ibid.).

[45] Weber S., *The Success of Open Source,* Harvard University Press, Cambridge, 2004.

[46] Open Source Definition, para 3: Derived Works: 'The license must allow modifications and derived works, and must allow them to be distributed under the same terms as the license of the original software. Rationale: The mere ability to read source isn't enough to support independent peer review and rapid evolutionary selection. For rapid evolution to happen, people need to be able to experiment with and redistribute modifications.'

[47] Kloppenburg, J., *First the seed: the political economy of plant biotechnology, 1492–2000,* Cambridge: Cambridge University Press, 1988.

Patent law requires full enablement disclosure, so that 'source code' – potentially including physical specimens of microorganisms – can't in principle be locked up, but must be available to the researcher; rights to research and experiment and the breeder's exception open up derivative uses of protected subject matter; the compulsory cross-licensing provisions of the EU Biotechnology Directive and the law of 'dependent inventions' amount to 'rights to use' patented technology, roughly akin to freedom to use derivative innovations.

These sketchy imprints of the software 'freedoms' or elements of open source even within the existing legislative structure recall the ambivalence about the level of address to policymakers: does the search for reformed innovation structures entail fundamental legislative reform, even treaty renegotiation; or reframing public-policy and public-interest interventions such as research funding and public research policies; or addressing the choices by individual researchers, institutions and firms. At the broadest international level, the objective for IP protection expressed in the WTO TRIPS Agreement poses an ethical and legal challenge: protection of IP 'should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'. It is difficult to take issue with this statement of a broad objective. Within this legal text, it surely guides the interpreter of the treaty to an inclusive view of public policy interests. But within the broader policy context, is it also a guide to the policymaker – an ethical heuristic? Hence, what kind of specific obligations might this suggest for those actively engaged in structuring the innovation infrastructure? To deliver on this promise for IP protection – and setting aside questions of formal treaty interpretation – there are many ways of construing this 'should': is it ethical in a deontological sense, expressing a duty incumbent on those engaged in protecting IP[48] or in a utilitarian sense, setting a test for legitimacy of policy choices within the TRIPS framework; is it consequentialist, providing a benchmark for the legitimacy of the actual outcomes of policymaking; or is it limited in ethical guidance, being strictly legal in character, establishing a formal obligation on policymakers bound by the treaty; or is it simply aspirational, more apposite for a preamble; or, most tantalising, is it predictive – a statement that the application of well-balanced IP mechanisms, implemented in line

[48] Recalling that TRIPS elsewhere views 'protection' in expansive terms as including 'matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed [in TRIPS].' (footnote to Article 3).

with the ensuing detailed standards, will *a fortiori* yield this outcome? In practice, this chapter may conflate into a general test of legitimacy, so flexible as to provide support for many diverse actual dispensations.

Similarly, although the frame of reference is more focused, it remains difficult to pin down a precise ethical basis to support the choice of innovation structures in the life sciences. If it is considered desirable to encourage the adoption of 'open source' or free innovation in the life sciences, what kind of ethical or legal argument applies?

- enlightened self-interest: it is good for you, it is a more efficient form of innovation that better serves your objective interests;
- ethical duty: you should behave this way, because it is inherently right to do so: perhaps because you would wish others to offer you the 'four freedoms',[49] and so the Kantian categorical imperative applies;
- strict utilitarian: it yields improved welfare outcomes for society overall;
- legal – you must do it by law, whether or not it is in your real or perceived interests, because of obligations either within IP law (noting the imprints of openness or freedoms found in IP law) or beyond IP law (such as the invocation of human rights or equitable obligations).

Each form of compulsion has been urged for 'open source' or free approaches to life sciences innovation. But does the nature of the 'should' depend on who and where you are? Recall that the essence of IP policymaking is setting what legally defined exclusivities over knowledge resources will advance innovation, fair competition and public welfare, and how those exclusivities should be shaped and governed. Some 'open source' ideas and some freedoms are hard-wired at the legislative level (or at least they can be) – this is at least the spirit of the enabling disclosure, for example, and the term limit on patents (I am not arguing that close congruence exists, not by any means, but identifying limited points of convergence). Individual holders of exclusive rights are also presented with a range of obligations – ethical and legal – and both self-interested and altruistic motivations. A complete analysis of a reformed innovation infrastructure in the life sciences would need to consider firstly how to promote the overall goals of innovation policy (broadly, both beneficial innovation and equitable access to the fruits of that innovation) within IP law, as a legal system; and secondly, to promote greater convergence with these goals of the

[49] By analogy with the freedoms identified by Stallman – the freedom to run a program; the freedom to study how it works through access to the source code; the freedom to redistribute copies; and the freedom to improve and distribute improvements (Stallman R. *The Free Software Definition*, 1996, www.fsf.org/philosophy/ free-sw.html).

actual outcomes from that system; and third, what modes and structures would most productively draw together providers/users of technologies, including the use of literal or metaphorical open source and free structures, so that their real and perceived interests, and the way those interests are pursued. This would close the ethical gaps between a hard consequentialist account (attaching value only to beneficial outcomes), deontological ethics or the ethics of doing one's duty (so that the ethically approved forms of behaviour do actually yield the desired outcomes), and legally permissible forms of IP and exercise of IP right.

4. Concluding comment: situating the infirmary and the granary between the cathedral and the bazaar

This discussion aims to illuminate pathways towards practical answers for the following core questions for life sciences policymakers:

(i) Is the only irresistible impetus to 'open source' or free in life sciences ultimately *technological*? Does leverage work essentially because the core (or seed) technology is so good – functionally good or economically attractive – or even effectively indispensable, in the case of unique research tools? Or is it a negative incentive – technology holdings stack up so that practical implementation of proprietary technology is literally unworkable (as occurred in the SNP case)? If the technology is the draw card, then the objective rationale for free/open life sciences may be circular, or recursive: as increasingly valuable technology is placed within this framework, the incentive to use the framework is strengthened. Looking back at the software example, Raymond suggests that a technological seed is essential: '… one cannot code from the ground up in bazaar style. One can test, debug and improve in bazaar style, but it would be very hard to originate a project in bazaar mode. Linus didn't try it. I didn't either. Your nascent developer community needs to have something runnable and testable to play with.'[50]

(ii) Are the infirmary and the granary neither 'cathedral' nor 'bazaar'? Although *in silico* and *in vitro* research pathways may cross and merge, the kind of life sciences research and development that moves close to delivering practical

[50] 'Necessary Preconditions for the Bazaar Style' in Raymond E., *The Cathedral and the Bazaar,* Thyrsus Enterprises, <thyrsus.com>, version 3.0 (2000).

products differs in key ways from software development. 'Release early and release often'[51] is unappealing for a new cox-2 inhibitor or glyphosate-resistant seed. And this is not merely a regulatory matter: it also concerns different needs for resources, infrastructure, ethical constraints and liability and risk management.

(iii) How to learn from and apply a technology-specific innovation model to a new field? Does one empirically reverse engineer 'open source' or free biotechnology from what has been shown to work in existing life sciences research, and port across models or even license text from the software field, or does one invoke models in the abstract, driven by ethical and broader considerations? If each of these three sources and approaches impels the review process, how does one absorb and integrate these disparate ideas and experiences while continuing to prioritise public interest objectives over particular models?

'Open source' or free research models offer pathways towards democratised innovation – democratised in participation, in its pluralistic directions, and in the distribution of opportunities and benefits. As broad models, they have resonances with long practice in many innovative contexts: many traditional or local technology users have long been read-write innovators. These models touch on issues that are of immediate concern for life science policymakers aiming to advance the public interest: reducing transaction costs for the creation of the bundles of technology and other inputs that define new life sciences products; broadening the scope of innovation to meet neglected needs; and for developing countries especially, strengthening domestic technological capacity and, where sought, technological autonomy and self-reliance.

But the prudent policymaker – with much at stake – will need a stronger objective base to work from, rather than reacting to proprietary models that are aggressively pursued by their principal corporate beneficiaries. Crafting innovation policy is broader in sweep than creating an asylum from monopolistic excesses, which can and should in any case be regulated directly. Open source or free innovation models in the life sciences may be understood and integrated within development strategies inasmuch as they confer systemic benefits. Failure to democratise innovation is not exclusively an artefact of the proprietary nature of rights over technology (system and application software) – the most neglected communities and obvious failures of

[51] 'Release Early, Release Often' in Eric Raymond, *The Cathedral and the Bazaar*.

innovation to deliver are situated where proprietary rights either do not exist or are practically unenforceable. Our natural, polemical tendency to structure debate through polarities might also overshadow the need to understand the complex interplay between proprietary and non-proprietary models of innovation and product development on a broader planning canvas when looking at the life sciences in the round – basic human needs and the production of public knowledge goods are most unlikely to be met exclusively through proprietary or non-proprietary approaches. The 'open source' debate in the life sciences is therefore valuable in exposing the weakness of this polarisation: exclusive or proprietary rights can be used to leverage access, to promote dissemination, to safeguard downstream use rights: the notion of promoting access through rights that exclude is indeed the underlying paradox of IP law and policy.

Whether and how benefits are obtained in practice depends on how skilfully any model is actually deployed and judiciously adapted, and on skills, resources and infrastructure: no innovation model or licensing structure is magic pixie dust; perhaps the single most damaging step a legal advisor can offer a research project is to reach for her folder of licensing precedents, as a shortcut for an objective appraisal of what broader goals the management of knowledge within the research programme should serve. Any viable open source project in the life sciences is likely to need good core technology and good technologists, clearly an abiding strength of reported open source software projects, and the innovation structure – including its formal legal underpinnings – will be built around what forms of interaction work best for the community of researchers and users (including those users who become sources of incremental innovations). The dissemination and analysis of models and metaphors can, nonetheless, stimulate new innovation practices and structures.

Even so, it is not a compelling need in life sciences innovation simply to construct, analyse and defend new or alternative innovation models for the sake of it; the core policy demands are to enhance, accelerate, decentralise and democratise life sciences innovation, to develop and disseminate more and more diverse useful products to wider groups of beneficiaries, and to reduce barriers to entry for researchers and to broaden the conception of research (for instance so that traditional medicine practitioners are recognised as true research partners in medical R&D[52] and so that the role of farmers in agricultural innovation and crop

[52] See, for instance, the Indigenous Knowledge Systems policy of the South African government and its application by the Medical Research Council.

improvement is more systematically recognized[53]). 'Open source' – or any other model – is not an end in itself, but should create pathways to better use of resources to meet more widespread needs. It may help break down illegitimate barriers and overcome poor, overly constricted approaches. But a fully equitable disposition of knowledge goods probably also requires the currently dispossessed acquiring some control afforded by proprietary structures or exclusive rights, to leverage their interests more effectively than purely through moral suasion and the expected benefits of technological diffusion. The open source debate in the life sciences is a reminder that, pragmatically, but also for the best ethical reasons, some degree of leverage over technology – even the use of exclusive rights to exclude overly exclusionary practices so as to protect a commons, or to sustain an enabling technology platform, may be necessary.

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[53] Consistent also with the articulation of farmers' rights in the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (Article 9), recognizing 'the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.'