Synthetic biology, patenting, health and global justice

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Abstract The legal and moral issues that synthetic biology (SB) and its medical applications are likely to raise with regard to intellectual property (IP) and patenting are best approached through the lens of a theoretical framework highlighting the “co-construction” or “co-evolution” of patent law and technology. The current situation is characterized by a major contest between the so-called IP frame and the access-to-knowledge frame. In SB this contest is found in the contrasting approaches of Craig Venter’s chassis school and the BioBricks school. The stakes in this contest are high as issues of global health and global justice are implied. Patents are not simply to be seen as neutral incentives, but must also be judged on their effects for access to essential medicines, a more balanced pattern of innovation and the widest possible social participation in innovative activity. We need moral imagination to design new institutional systems and new ways of practising SB that meet the new demands of global justice.

Keywords Co-construction · Co-evolution · Access to knowledge · Gene patents · Global justice · Health impact fund

Introduction

Forecasting is a rather hazardous exercise, especially if the aim is to predict the future. Any sketch of the likely development of synthetic biology (SB) in the near and more remote future is speculative, as would be an outline of expected trends in patent law. So an exercise in which

these two forecasts or explorations are to be combined, would be doubly speculative. The problem becomes even worse if we have to zoom in on the *medical applications* of SB and the legal and moral issues they are going to raise with regard to intellectual property and patenting—because it is not yet very clear what medical applications may stem from SB in the short and middle term (for an overview of some ongoing developments in this field of application, see Ruder et al. 2011). Proponents admit that the field is still in its infancy and has yet to overcome some major technological challenges. These include the need to improve and accelerate the design cycle and to move beyond microbial systems (on which current work in SB is still focused) towards mammalian systems, especially when the aim is to develop therapeutic applications for human health (Khalil and Collins 2010). International patent law is at present also very much in flux. There are ongoing debates on what types of discoveries or inventions in the life sciences actually are (or should be) patentable and the economic and political pressures on companies and research institutes to either adopt vigorous patenting strategies or alternative, more ‘open’ policies are shifting.

What then would be the best approach to tackle the legal and moral issues raised by SB and its medical applications with regard to intellectual property and patenting? My preferred strategy would be a two-pronged approach.

On the one hand I would like to put contemporary developments in an historical perspective. This provides some immunity against the hypes and exaggerated expectations that inevitably surround a new field like SB. The rise of SB can be seen as a continuation, and provisional culmination, of some longer-term trends that are characteristic of major strands in western science and technology, e.g. the “informatisation” of life since the beginnings of molecular biology or the attempted implementation of the

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Kant-Vico-Feynman principle “What I cannot create I do not understand”, which has previously been followed in organic chemistry (Van den Belt 2009). Another recognized source of inspiration is electronic engineering, from which the key concept of “circuits” has been adopted. SB is also a continuation and radicalization of genetic engineering or biotechnology. Thus there is historical continuity as well as discontinuity. That also applies to the development of patent law (or more broadly intellectual property law). It is very important to realize that the history of intellectual property rights (IPRs) is a history of contestation (May and Sell 2006, 37ff), so as to avoid the widely held misconception that IP issues have become controversial only recently.

The other prong of my two-pronged approach would be to stress the need for an ethical analysis that takes the fact that we live in a globalized and interconnected world utterly seriously. With the emergence of a *de facto* global IP regime, it is no more than reasonable to demand that the justification for IPRs also be cast in global terms. We should definitely look beyond the typical interests and concerns of a single nation-state. Thus the normative aim of global justice must be a leading consideration for the design and reform of the international IP system (as it is taken, for example, by Thomas Pogge and other advocates of the Health Impact Fund). It might also be necessary to give free reign to the moral imagination (e.g. by proliferating possible scenarios for the future of IP and the life sciences, as was done by a major study commissioned by the European Patent office: see EPO 2007). As IPRs increasingly cover the strategic assets of the knowledge economy and information society (including the ‘bio-information’ goods of medicine, food, agriculture and bio-energy), they become deeply implicated in essential requirements for the sustenance and flourishing of human life. Patent lawyers and other IP scholars have been slow to abandon their narrow utilitarian preoccupation with the “incentivizing” role of IPRs for a more imaginative approach that also attends to the cultural significance of IP law, especially with regard to how it affects people’s capacity to participate in cultural production including science and technology (Sunder 2012). Resorting to moral imagination would furthermore be justified as a proper response to the optimistic and rather hubristic claim advanced by SB enthusiasts that the potential of this new field is limited “only by the imagination of researchers and the number of societal problems and applications that SB can resolve” (Khalil and Collins 2010, 377). If it is indeed true, as Craig Venter stated in 2010, that “we are entering an era limited only by our imagination”, then this would also appear to provide SB researchers with ample strategic opportunity to raise hyperbolic claims and grandiose expectations. I want to confront the exuberant imaginative rhetoric of synthetic biologists with the sobering insights of

historical contextualization as well as a modest attempt to exercise moral imagination.

In a sense, this two-pronged strategy is making a virtue out of necessity, as I openly acknowledge that the future is radically uncertain. The two prongs of my approach are held together by an historically informed interpretation of the current international situation in IP law as representing a major political contest between two frames, namely the “IP frame” and the “A2K frame” (access-to-knowledge frame) (Kapczynski 2008; Shaver 2009; Krikorian and Kapczynski 2010). The first frame holds that intellectual property rights like patents, copyright and plant breeders rights are a just reward for those who have expended creative effort in realizing inventions, artistic works and other innovative products and that the prospect of such exclusive rights constitutes an indispensable incentive for future innovative activities. The adherents of this frame also assume that you cannot have too much of a good thing too readily, so that if intellectual property is good, *more* intellectual property is even better. The second frame questions the assumption that exclusive rights are always indispensable for invention and innovation by referring to the contrary experience with free and open-source software in recent decades. It also points to the importance of access to existing knowledge and information as essential inputs for further innovation. Its adherents finally hold that human rights (like the right to health, to adequate food, to education and to participation in cultural life and scientific advancement) should never be subordinated to the protection of IP rights. The first frame has dominated the past three decades, but the second frame is in the ascendant.

Technology-neutrality of patents versus “co-construction”

The debate on SB and patents is often predicated on the prior assumption that the patent system is, or should be, “neutral” with regard to the kind of technologies for which legal protection is being sought. This neutrality is even enshrined in the TRIPS agreement. Article 27.1 states that “... patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application”. Thus in a publication on SB and patents, EPO official Berthold Rutz remarked: “One of the reasons for the long-lasting success of the patent system is its *non-discriminatory character*. The same basic patentability criteria apply to all fields of technology: novelty, inventive step and industrial application” (Rutz 2009, S14).

I think the technology-neutrality of the patent system is a myth. There has never been a patent system that is completely or even approximately “technology-neutral”,

nor can there be such a system. The myth presumes that the three basic requirements can be applied to any newly emerging field of technology in a straightforward and “mechanical” way, without needing much additional interpretation. As a matter of fact, there are notable discrepancies in the interpretation of the requirement of inventive step (or non-obviousness) across different technologies like biotechnology and software, along with equally striking divergences in the interpretation of the additional requirement of disclosure (written description, enablement). Indeed, as two prominent patent lawyers conclude from these systematic differences, “while patent law is technology-neutral in theory, it is technology-specific in application” (Burk and Lemley 2002, 1156).

Against the myth of technology-neutrality we can put the idea of the “co-construction” or “co-evolution” of technology and patent law. In science and technology studies (STS) it is indeed not unusual to conceive of the relationship between science/technology and society (or the social, legal and political order) as one of mutual shaping, thus avoiding the extremes of scientific/technological determinism and social determinism (MacKenzie and Wajcman 1998; Jasanoff 2004). When a new field of technology emerges, patent law does not provide a list of ready-made criteria by which the technical accomplishments in the new field can be judged as patentable inventions. Instead, the conditions of patentability have first to be worked out and elaborated vis-à-vis the new technology, if only because the notion of “invention” is not strictly and universally defined but open to historically variable interpretation. Thus with the rise of synthetic dye chemistry in the second half of the nineteenth century decisions had to be made about the precise meaning and scope of “a *particular* process” to which the German Patent Act of 1877 had limited the patentability of chemical inventions; or on how high (or rather low) the bar for inventiveness had to be put to allow the patenting of “inventions” routinely produced on a large scale by the new R&D laboratories of the chemical industry (Van den Belt and Rip 1987). As a major stakeholder, the German chemical industry often lobbied vigorously to influence the shaping of patent law (Dutfield 2009).

The development of patent law and biotechnology provides another clear example of “co-construction” or “co-evolution”. The first question to be answered was if this part of law applied at all to this new area of technology. In the landmark case of *Diamond v. Chakrabarty* a 5-to-4 majority of the US Supreme Court held in 1980 that anything new under the sun that is made by man, whether living or non-living, can in principle be patented. Chief Justice Burger argued on behalf of the majority: “[T]he patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is

not nature’s handiwork, but his own; according it is patentable subject matter under § 101.” This verdict occasioned a huge capital influx into the emerging biotech industry in the following years.¹ During the 1980s the patentability of living organisms was further extended from bacteria to multi-cellular organisms and to higher plants and animals (cf. the “oncomouse” patent of 1988). Equally important for the biotech industry was that patents on isolated and purified genes and DNA sequences have also been recognized as legally valid. The reasoning behind this view was that a gene is just a chemical compound and that the isolation and purification of a particular DNA sequence from the body turns it into something radically different from its natural state and thus into an invention eligible for patenting.² This doctrine would seem to be a rather thin justification—the Australian jurist Luigi Palombi disparagingly calls it the “isolation contrivance” (Palombi 2009, 205–225)—but nonetheless it has provided the legal underpinning for the practice of granting gene patents by the US, European and Japanese patent offices for more than two decades. By 2005, it was found that some 20 percent or one-fifth of human genes had already been captured by US patents (Jensen and Murray 2005). One can therefore imagine that the decision by Judge Robert Sweet on May 29, 2010, in the high-profile case against the patents of Myriad Genetics on the BRCA1 and BRCA2 genes related to breast and ovarian cancer, must have sent shock waves through the entire biotech industry. Judge Sweet dismissed the isolation doctrine as a “lawyer’s trick” and declared that human genes constitute unpatentable subject matter (Schwarz and Pollack 2010). The US biotech industry was understandably relieved when a higher court (the Court of Appeals for the Federal Circuit, a specialized patent court that is well-known for its pro-patent stance) reversed this decision in late July 2011, but then the plaintiffs appealed to the Supreme Court. On March 26, 2012, the latter sent the case back for consideration to the appeals court, which on August 16, 2012 reaffirmed Myriad’s right to patent the “isolated” genes (Reuters 2012). This will probably not be the end of the saga.

While patents on DNA sequences are recognized in many jurisdictions, it is a moot question whether or not the

¹ Together with the Bayh-Dole Act of 1980, which allowed universities to take out patents on the results of federally funded research, it also led to a rapid commercialization of molecular biology. In the introduction to his novel *Jurassic Park*, the late Michael Crichton wrote in 1991: “The commercialization of molecular biology is the most stunning ethical event in the history of science, and it has happened with astonishing speed”.

² This view is often presented as if it were a logical consequence of the Chakrabarty decision, but Palombi argues that the case for patents on isolated and purified genes would not pass the US Supreme Court’s criteria, as such genes do *not* have “markedly different” characteristics from their natural counterparts (Palombi 2009).

TRIPS agreement actually obliges WTO member countries to make legal provision for the patentability of DNA. A report for the World Health Organization notes that “there is ambiguity as to whether TRIPS requires countries to grant patents on DNA sequences” (WHO 2005, 50). Proponents of DNA patenting could point out that the agreement demands that patents shall be available for any inventions in all fields of technology (art 27.1) and that DNA sequences are not explicitly mentioned among the exceptions allowed by article 27.3.b. Opponents, by contrast, could argue that TRIPS does not offer a definition of the key concept of “invention” and that it is by no means established that isolated genes and DNA sequences are to be considered inventions rather than discoveries. The WHO report concludes that “countries are free to judge for themselves whether the excludability of DNA is inferred” (WHO 2005, 17), although it also warns developing countries that want to avail themselves of this ambiguity for possible reprisals from the developed countries: “In light of current practice in most economically advanced countries, and the present trend towards expansive IP coverage, it is important to point out that this is a controversial option” (WHO 2005, 44).

From about 1980, modern biotechnology has “co-evolved” not just with patent law, but also with other parts of the social and political order. Indeed, the extension of patentable subject matter to include genes and DNA sequences, cultivated cells and tissues and transgenic organisms was itself part of a wider movement of strengthening and extending intellectual property rights (not just patents, but also copyright and plant breeders rights) on national, regional and worldwide scales that fitted well with a neoliberal agenda of privatization, globalization and the reduction of the public sector. Indeed, as two IP scholars note, “it was natural for free-market ideologists to favor an expansion of intellectual property rights” (Landes and Posner 2004, 23). In recent years, however, this dominant “IP frame” is increasingly challenged by the “A2K frame” or “access-to-knowledge frame” (Kapczynski 2008; Shaver 2009; Krikorian and Kapczynski 2010).

An interesting corollary of “co-construction” or “co-evolution” between technology and patent law is that it could lead to *path effects* that may in turn give rise to *mismatches* between subsequent technologies and intellectual property regulation. Thus the proliferation of patents covering hundreds of thousands of genes or DNA sequences on the human genome and the genomes of other organisms, a direct outcome of the prior “co-evolution” of classical biotechnology and patent law, might constitute an obstacle for the development and application of new technologies like DNA-microarrays (“gene chips”) and whole-genome sequencing. At present the legal situation is

still highly uncertain: “Promising new methods for full-genome analysis might or might not face patent infringement liability” (Cook-Deegan 2011, 874; for a more skeptical assessment, see Holman 2012). SB will also have to confront the legal legacy of the biotech gold rush.

The BioBricks approach: an ethos of sharing

It is not difficult to understand why patents could be a major threat to the realization of that particular strand of SB that aims at the construction of complex biological systems on the basis of well-defined standard parts, i.e. genetic sequences with known functions that can be used as building blocks in biological syntheses. Construction of one biological system may easily require hundreds or even more than 1,000 different components. If only a small percentage of the needed parts were encumbered with patents (or other IP constraints), it could become prohibitively costly to obtain “freedom to operate” to assemble the entire system. A patent thicket would doom the prospects of this strand of SB: “One roadblock to SB’s future is the messed-up patent environment in biotech, where every tiny protein pathway and gene sequence has an owner wanting to get paid ... [U]nless basic components are made freely available it will be too expensive to make anything useful or complex” (Herper 2006).

Deeply worried that their fledgling field could be smothered already in its cradle, several SB enthusiasts from MIT, Harvard and the University of California have set up the *BioBricks Foundation*, which administers the Registry of Standard Biological Parts, a steadily growing online collection of parts on which SB practitioners (including the students who participate in the annual iGEM competitions) can draw at will to engineer new life forms and to which they can contribute their own components. From the outset leaders of the field like Drew Endy and Tom Knight have also been groping for suitable legal instruments to ensure that BioBrickTM standard biological parts remain freely available to the SB community. They have been inspired by the open source movement in software development, which uses copyright law in a creative way by devising licenses like the GPL or General Public License (“copy-left”) to ensure that newly written software code is not privately appropriated but remains free to use for all. The problem for SB is that legal devices like the GPL that are based on copyright law cannot easily be transferred to the biological field, where the dominant form of IP is not copyright but patents. “Unlike copyright”, as the BioBricks Foundation explains on its website, “patents have high transaction costs” (BioBricks Foundation 2012). Filing patent applications for all the standard parts of the collection alone would cost tens of millions of dollars. Due

to its “viral” effect a GPL-like license might also be considered too strong in that it would prevent the patenting of any final products such as pharmaceuticals that could be made by SB methods. It is all very well to keep the basic tools and building blocks freely available to the research community, but some synthetic biologists argue that such a viral effect would be undesirable as IP protection is still a cornerstone in our current system of pharmaceutical innovation. The legal experts Arti Rai and James Boyle advised the SB community to follow the example of the (public leg of the) Human Genome Project and make new building blocks publicly available as soon as possible: “Placing parts into the public domain not only makes parts unpatentable, but it undermines the possibility of patents on trivial improvements” (Rai and Boyle 2007, 392). This strategy does not provide a watertight guarantee, however, that such parts will be preserved for the public domain or the commons. It is not certain either whether the parts that are already in the Registry are unencumbered by any patent rights. On a workshop held in Berkeley on March 31, 2006, Drew Endy estimated or rather speculated that perhaps one-fifth of BioBricks parts were patented. So it is not unthinkable that in future when SB yields commercially interesting applications in the fields of health, energy or bioremediation, “patent trolls” claiming intellectual ownership of some of the used parts may suddenly turn up to assert their rights. In October 2009 the so-called *BioBrick™ Public Agreement* (BPA) was proposed as a new legal framework for regulating the rights and duties of the contributors and users of the parts collection. Basically, what it comes down to is that “the Contributor makes an irrevocable promise not to assert any intellectual property rights held by the Contributor against Users of the contributed genetic functions” (BioBrick Foundation 2012). The BPA is a scalable contract actually made up of two separate agreements, the Contributor Agreement and the User Agreement. Whereas the former binds the contributor of BioBrick parts not to assert IP rights over these parts against any user who has signed the agreement, the latter obliges the user to provide attribution to the contributor, where requested, and to respect biological safety practices and applicable laws. The BPA has no viral effect, so it does not prevent users employing parts from the collection to patent any final products they may develop from these starting materials. One might question whether this proposed arrangement provides sufficient incentives for potential contributors to donate their materials to the Registry (Henkel and Maurer 2009, 1097).

There is no doubt that the synthetic biologists who established the BioBricks Foundation are strongly committed to open-source principles and an ethos of sharing, but they too are forced to accommodate to the realities of an IP-dominated world. Their attempt to carve out a little

niche of a commons comprising the building blocks and basic tools of their trade thus continues to rest on a somewhat fragile legal base. As Drew Endy declared in 2011: “The decision to use a non-assertion promise rather than a licensing agreement was a complex one that involved careful consideration of the different legal and financial landscapes around patented uses of genetic materials rather than copyrighted software. The simplicity of the BPA should help the community of synthetic biologists grow without the cost or complexity to navigate the patent system. Those who wish to continue to use the patent system and other intellectual property frameworks (outside the sharing system established via the BPA) are free to do so” (Endy 2011).

Some basic research tools or building blocks that are not actually part of the Registry of Standard Biological Parts would certainly be welcomed as an addition to the toolkit of the SB community if only their proprietary status were no obstacle. A case in point is the so-called zinc finger technology that is covered by a strong patent portfolio owned by the Californian biotech company Sangamo BioSciences, although its control over the field is partially challenged by the academic Zinc Finger Consortium that aims to develop alternative “open-source” zinc finger technologies to increase public access (Chandrasekharan et al. 2009). Zinc finger proteins form a broad array of sophisticated molecular tools that can target and cut DNA sequences at specific binding places. In 2011 the student team of Harvard University that took part in the iGEM competition decided to help tilt the balance a little more in favor of open access by developing a novel method for the production of custom zinc fingers for targeting new binding sequences. The Harvard students claimed that their contribution “would greatly increase the accessibility of zinc finger technology and help to overcome the prohibitively high price tags of the present market” (Harvard iGEM team 2011). They pointed out that the cost of purchasing a single zinc finger protein from Sangamo could be up to \$15,000. The company also imposes further restrictions on academic researchers for the use of zinc finger technology. In the ‘human practices’ (ethical, legal and social) part of the assignment, the Harvard student team raised the issue of IP protection versus open source and pleaded for “the necessity of balance in intellectual property rights and the promotion of open-source technology for optimal benefit to all” (ibid.). The team also sent letters to senators and representatives to raise awareness among policy-makers on this issue.

Craig Venter’s model of proprietary science

The BioBricks approach is not the only strand in SB. There is also the “chassis school” represented by Craig Venter

and his team. Their favored procedure is to assemble a “minimal genome” (i.e. a microbial genome stripped of all dispensable genes) from synthesized DNA, transplant it into a recipient cell whose own genome has been removed, and use the artificial creature thus obtained as a “chassis” upon which all kinds of economically useful genes can be mounted. On 31 May 2007 the US Patent and Trademark Office caused a stir when it published the patent application that the J. Craig Venter Institute had filed in October 2006 on a new artificial life form called *Mycoplasma laboratorium* (US Patent Application 20070122826, filed 12 October 2006). The announcement was somewhat premature, because the first artificial creature was only to see the light of day almost 3 years later, on 29 March 2010. However, the claims of the first patent application, to which other applications would follow, were already quite sweeping. They are formulated successively as of increasingly wider scope. Thus the set of 381 essential genes making up a “minimal bacterial genome” is being claimed (claim 1); the synthetic organism that can be made from these genes; any variant of the organism that can produce ethanol or hydrogen (claim 20); any scientific method for assessing the functions of genes by inserting those genes into the synthetic organism (claim 22); and any digital version of the synthetic organism’s genome (claim 19). Among the intended applications the creation of synthetic organisms for the production of biofuels like ethanol and hydrogen is particularly emphasized. At present, such applications may sound futuristic, but it seems that Venter wants to signal to the general public that his enterprises (consisting not only of the nonprofit *J. Craig Venter Institute* but also of the private company *Synthetic Genomics, Inc.*; patent rights will all be assigned to the latter) intend to play a key role in solving the urgent problems of energy supply and climate change. In his Richard Dimbleby Lecture delivered on 4 December 2007 on BBC One, he went so far as to suggest that SB may save the world and effectively constitute humanity’s last chance for survival (Venter 2007).

Contrary to the BioBricks school, which attempts to establish a practice of sharing inspired by open-source models in software development, Venter continues the strategy of aggressive patenting of classical biotechnology with a vengeance. The two strands of SB thus illustrate the tension between the old “IP frame” and the new “A2K frame”.

The suite of patents that the J. Craig Venter Institute subsequently filed also have very broad claims. John Sulston, Venter’s old rival in the race to sequence the human genome, sounded the alarm on the extremely wide scope of the claims in the patent applications, suggesting that they might, if granted, give Venter’s enterprise a monopoly on a wide range of techniques (Chan and Sulston 2010). James

Boyle also warned that Venter might become “a monopolist over the code of life” and that the efforts of the BioBricks community to create an open source collection of standard biological parts might be endangered by “the threat of overbroad patents on foundational technologies” (Boyle 2010).

Let us assume, for the sake of the argument, that the plans of Venter’s company Synthetic Genomics Inc. to develop highly advanced “fourth-generation” biofuels using carbon dioxide as feedstock will indeed come true and that the new techniques as a matter of course will be heavily protected by patents. This would conjure up the morally problematic scenario in which technological solutions that might be humanity’s last hope for survival (as Venter himself suggested in his lecture before the BBC) are locked up in patents that serve to make them inaccessible to any but the most wealthy users. The company will have to tell its impecunious non-clients: “Sorry, you won’t be saved, if you are not willing to pay the price of your survival!”. But in this case, unlike the users of high-priced patented medicines that are effectively denied to poor patients, the wealthy users of expensive high-tech biofuels won’t be saved either. Climate change will not be sufficiently mitigated if only the wealthy inhabitants of the earth use “climate-neutral” energy. In ongoing international negotiations, the US government also takes the position that patents and other IPRs should be kept out of the debate on climate change actions. Global warming is apparently perceived more as a major business opportunity for American companies to earn huge profits in the emerging market for climate mitigation and adaptation technologies and less as a common threat to humankind which may call for the timely sharing of advanced clean technologies on non-commercial terms. However, without reforms of the global IP regime, developing countries will not be able to realize the actions required to avert this common threat (Rimmer 2011).

Important medical applications of Venter’s SB approach are expected in the area of vaccine development (Glass 2011). In October 2010 his institute and his company set up a new venture, *Synthetic Genomics Vaccines Inc.* (SGVI), in collaboration with the Swiss pharmaceutical company Novartis, to develop next-generation vaccines. The J. Craig Venter Institute will bring its synthetic genomic research expertise to this venture, “coupled with the intellectual property and business acumen of SGI [Synthetic Genomics Inc.]” (press release October 7, 2010). The direct aim of the venture is to accelerate the production of the influenza seed strains required for vaccine manufacturing, so that the time needed to start vaccine production can be cut short by 2 months (with the so-called swine flu “pandemic” of 2009 serious vaccine production only got started after the peak of the “pandemic” was over). This is a respectable aim, of

course (though one might question whether the world might be “prepared” in time if a pandemic outbreak of the rapidity and seriousness of the Spanish flu of 1918 would strike again, even with a time saving of 2 months). There is no doubt, however, that the new venture will pursue a strategy of aggressive patenting. Yet the area of vaccine development for influenza epidemics is precisely an area where intellectual property rights clash with global public health needs (Andrews and Shackelton 2008). Under the rules of the WHO countries affected by flu outbreaks are expected to send samples of viruses to the WHO’s collaborating research centers and laboratories, which are all located in the USA, Europe or Japan. These laboratories cooperate with western pharmaceutical companies that take out patents on genetic sequences and vaccines derived from these virus samples (for an expert report on patentability issues related to viruses, see WIPO 2007). Developing countries contributing samples to the WHO are often unpleasantly surprised when they subsequently find out that they cannot afford the patented vaccines that are developed from these materials. No wonder then that in 2007, during the avian flu epidemic, Indonesia refused to further share its H5N1 virus samples if it would not get access to affordable vaccines (Fidler 2008; Hammond 2009). This is a very serious threat as worldwide sharing of virus samples is a vital requirement for the effective working of WHO’s Global Influenza Surveillance Network. Within the WHO parties are still negotiating about access and benefit-sharing arrangements for virus samples and vaccines.

As the above examples of biofuels and vaccines illustrate, we have to consider patent issues in the broader context of sustainable development and global health and global justice. Moreover, the traditional justification of intellectual property rights as indispensable incentives for innovation is increasingly challenged as alternative models have emerged in the wake of the open-source movement. Chan and Sulston put the controversy over Venter’s patents in the perspective of an epochal confrontation between the IP frame and the A2K frame: “The conflict between private interests in science, protected by patents and cloaked in secrecy, and open access research remains one of the most contentious issues in modern science *and affects us all*” (Chan and Sulston 2010, 1316; *italics mine*).

Patents, health, and global justice

SB is thus clearly at a crossroads: will it predominantly follow the open access approach of the BioBricks school (in line with the A2K frame) or will it more widely adopt Venter’s model of proprietary science (in line with the IP frame)? It is still too early to discuss the potential medical applications of SB and the ethical and legal questions they

would raise with regard to patenting in concrete detail. However, an intense international debate is already going on about the ethical implications of patents in the pharmaceutical area in terms of the human right to health, access to essential medicines and global justice. This wider debate partly sets the terms for the debate on the role of the two models in the future of SB.

At first sight the requirements for pharmaceutical innovation seem to strongly support the IP frame. “Pharmaceuticals”, as US lawyer Richard Posner declares, “are the poster child of the patent system” (Posner 2012). It generally takes hundreds of millions of dollars to find and develop a new medicine (including the costs for the animal tests and clinical trials that have to be done to obtain market approval from the regulatory authorities)—an 2003 estimate put the average cost at \$802 million (DiMasi, Hansen and Grabowski 2003). Once a new medicine is on the market, however, it can be reverse-engineered or copied relatively easily. Who would under such circumstances invest in pharmaceutical R&D if he had no prospect of protecting the products of his research against potential rivals? Pharmaceutical companies in America and Europe claim that the rationale that patents are indispensable incentives for pharmaceutical innovation also holds on the global level. Their lobbyists were among the main drivers and architects behind the TRIPs Agreement of 1995. Not surprisingly, this international treaty prohibits any country to exclude medicines from patentability.

The flip side of worldwide drug patenting is that millions and millions of poor patients are doomed to die prematurely while the patented medicines that could save their lives or alleviate their suffering are beyond their reach due to high monopoly prices (Forman 2007). It was the global HIV/AIDS crisis that first raised widespread awareness about this moral drama, after western pharmaceutical companies had been emboldened by the TRIPs agreement to assert their enhanced IP rights with more vigor than before. NGOs like Oxfam and Médecins Sans Frontières promptly reacted by mobilizing international public opinion and exerting moral pressure on the companies to lower drug prices. In the Doha Declaration of 2001, developing countries “reaffirmed” that the TRIPs agreement allowed them to issue compulsory licenses on patented drugs for reasons of public health, although it still requires much courage to take this step as it usually evokes reprisals from the US or the European Union. At any rate, both through relentless NGO pressure and perhaps also through the implicit threat of compulsory licensing, prices for HIV/AIDS medicines in developing countries have dropped enormously in the past decade.

It is however clear that a more durable solution to the moral dilemmas around drug patents is still wanting. The German philosopher Thomas Pogge, a specialist on the

ethics of global justice, has given much thought to this problem (Pogge 2005; Hollis and Pogge 2008).³ He insists that access to essential medicines is a basic human right that cannot be sacrificed on the altar of pharmaceutical innovation. On the other hand, the development of new drugs for the future needs of humanity also has to be safeguarded. In this regard another problem has to be overcome simultaneously, to wit, the one-sided orientation of the current pharmaceutical innovation system towards the needs of the wealthy and the affluent, as is epitomized by the well-known 10/90 gap: “Only 10 percent of global health research is devoted to conditions that account for 90 percent of the global disease burden” (Drugs for Neglected Diseases Working Group 2001, 10). Pogge holds that any attempt to re-design the international patent system according to principles of global justice thus has to solve the twin problems of *availability* (effective medicines have not been developed for many diseases and conditions prevalent in developing countries) and *access* (the poor cannot afford to buy the medicines that are available on the market) simultaneously. His proposed institutional solution, elaborated together with economist Aidan Hollis, goes by the name of the *Health Impact Fund* (Hollis and Pogge 2008).

The idea is that the Health Impact Fund, an international public fund based on contributions from developed countries, should be established to create the possibility of rewarding pharmaceutical companies for developing essential medicines, the size of their reward being proportional to the impact of their invention on the global disease burden. In essence, the scheme means that companies are offered a choice. Once they have taken out a patent for a new drug, they can either attempt to earn money on it in the usual way by exploiting the monopoly and setting prices that affluent markets can bear, or they can choose the option of registering with the Fund and being rewarded according to a formula that is geared to the health impact of the new drug (measured in terms of QALYs, i.e. the number of quality-adjusted life years saved worldwide). In the latter case the drug will have to be made available at an administered price that is set by the Health Impact Fund to reflect average manufacturing and distribution cost. In return the registrant will receive, after market approval of the new medicine, annual reimbursements from the Fund that are

proportional to the global health impact of the drug for a period of 10 years. After this period the medicine will be freely available for generic producers. Setting an administered price at roughly the level of average manufacturing and distribution cost will ensure that the problem of access is also addressed, at least for drugs registered with the Fund. (For a detailed exposition of the whole scheme, see Hollis and Pogge 2008).

Several commentators have questioned the political and practical feasibility of the Health Impact Fund. One critical issue is funding. The whole initiative needs initially some 6 billion dollars from governments or other contributors to take off. Will such funds really be forthcoming and can pharmaceutical companies base their long-term R&D decisions with any confidence on government pledges to provide funds over a longer period of time (Buchanan, Cole and Keohane 2009)? It has also been pointed out that the measurement procedure for assessing the impact of a new medicine on the global disease burden is rather complex, which would make the assessment vulnerable to corruption (Sonderholm 2010). Others think the Fund is too friendly to the pharmaceutical companies in that it offers them a big additional carrot in order to “seduce” them to invest in neglected diseases, while its originators simultaneously dismiss the main remedy developing countries have to ensure access to medicines, compulsory licensing, as a disincentive that may undercut the whole scheme (see Hollis and Pogge 2008, p. 99). It would be politically unwise, however, to give up this vital remedy in exchange for the uncertain future outcomes of the Fund (Love 2008).

Here I would like to draw attention to another critical feature of Pogge’s reform proposal, namely the notable fact that the whole scheme still relies very strongly on the “incentivizing” effect of patents. The main problem with the present patent system, in Pogge’s view, is that the incentives are geared to (potential) market demand in wealthy countries that is backed up by purchasing power. The “trick” of Pogge’s scheme is to leverage the unmet medical needs of the South by backing them up with additional funds, so that they too carry some weight in the market pull directing pharmaceutical innovation. It is all a matter of setting the incentives “straight”—but by the same token the scheme still counts on the role of patents as incentives.

Pogge’s reliance on patents dovetails with the received view of the pharmaceutical industry as the preeminent example of a sector where patents are indispensable for innovation, due to high investment costs of R&D and the relative ease to reverse engineer any resulting product. Lately, however, the presumed “incentivizing” effect of patents even for the pharma sector is increasingly called into question. For one thing, the track record of the industry over the recent period is not particularly impressive (even

³ Pogge’s reform proposal for pharmaceutical innovation is only one of the many schemes aiming at a better alignment of drug research and development with the medical needs of the poor that are currently on offer. It has been selected for special scrutiny here because it is inspired by an explicit conception of global justice, is less piecemeal and more comprehensive than most alternatives, and because it is in my view also exemplary in its shortcomings. For a survey of various alternative schemes, see Nathan (2007) and DeCamp (2007, 320–396).

apart from the global imbalance epitomized in the 10/90 gap). Official figures show that in the last three decades “the productivity of the pharma R&D enterprise—the number of new molecules brought to market per dollar spent on R&D—has declined markedly” (Grootendorst 2009, 2). Ironically, according to Grootendorst’s hard-boiled economic analysis, it is the patent system itself and the very high profit margins that it generates, which are to blame for a massive waste of economic resources—a lot of effort is simply spilled by patent holders on keeping other rent-seekers at bay.

Thus there is every reason to question Pogge’s assumption that patents are indispensable as incentives for innovation. For the adherents of the A2K movement there is, of course, nothing extraordinary in this conclusion. It seems that Pogge got stuck half-way between the IP frame and the A2K frame. Although his Health Impact Fund aims to provide affordable access to the final products of pharmaceutical innovation and to influence the direction of innovative activity, it does not address the fact that most pharmaceutical patents are possessed by only a handful of western drug companies. For the adherents of the A2K movement, however, this concentration of control over innovative activity in the hands of a limited number of big players is a major concern (DeCamp 2007, 316). Access to knowledge, after all, is crucially about *participation* in the global networked knowledge-and-information economy. The right to actively participate in scientific advancement, not just to passively share in its benefits, is also enshrined in article 27.1 of the Universal Declaration of Human Rights. For the A2K proponents this is a very important human right (Shaver 2009).

One might object that such vistas of a much more widely based participation in medical advancement and pharmaceutical innovation are merely utopian dreams. It would seem that the enormous capital costs for research, development and market approval are simply too high a barrier for many potential candidates to enter this field. However, the costs of clinical trials account for more than half of the oft-cited average amount of \$802 million (DiMasi, Hansen and Grabowski 2003; Grootendorst 2009). Pharmaceutical companies invoke these huge costs as a justification not just for strong patents, but also for exclusive rights over safety and efficacy data submitted to regulatory authorities, known as “market exclusivity” in the US and as “data exclusivity” in the EU. Such exclusive rights constitute an extra layer of (quasi) intellectual property protection in addition to patents. Due to this double protection, producers of generics can still be prevented from entering the market as long as they, or rather the regulatory authorities, are not allowed to refer to the relevant data previously submitted by originator companies, even if the latter’s patents have meanwhile expired or

been declared invalid. Since the TRIPS agreement of 1995, the USA and the EU try to impose similar regimes of data exclusivity on developing countries, although sometimes meeting with stiff resistance (e.g. from India). Pharmaceutical companies also increasingly resort to this form of protection (Roemer-Mahler 2012). In a global context, data exclusivity is still a highly contested issue. One could actually make a strong case for the view that information on efficacy and safety of medicines should not be treated as a private good at all, but as a national and global public good (Reichman 2009). Public funding of the needed safety and efficacy testing would avoid moral hazards resulting from inbuilt conflicts of interest and enhance the credibility, trustworthiness and quality of the data. It would also lower the costs for private companies to engage in innovative activities. Such a reorganization of clinical trials would therefore also be instrumental in considerably lowering the entry barriers for participation in pharmaceutical innovation. The point is that we should not uncritically accept the current extremely high costs of conducting pharmaceutical research and development as inevitably required by the nature of the activity itself. Nonetheless, there is no denying that pharmaceutical innovation continues to offer a serious challenge to the participatory ideals of A2K proponents. It would take a fair measure of practical ingenuity, moral imagination and political will to devise and implement alternative ways of conducting pharmaceutical research that allow much wider participation from developing countries.

Ultimately, however, the widest possible participation in culture (including science and technology) is what development is all about. IP scholar Madhavi Sunder formulates this view as follows: “... participation in the production of the world’s knowledge is an end in itself. All human beings seek to ‘think for themselves’, to apply their ingenuity to better their own lives and the lives of those around them. This is *what development is for*. Amartya Sen’s agency-oriented conception of development as freedom recognizes that individuals in the developing world do not simply wish to sit back and be the ‘beneficiaries of cunning benefit programs’, but rather seek to enhance their capacity to live a life that is happy and fulfilling, to care for themselves, and to interact with others, near and far” (Sunder 2012, 178).

SB and IP once again: co-evolution and participation

Against the myth of the technology-neutrality of the patent system, I put the idea that there is a ‘co-construction’ or ‘co-evolution’ of IP law and technology. Can this analytical framework give us some guidance on how to orchestrate the co-evolution between SB and IP in such a way that

it contributes in the context of global public health to a just development? And what would be the potential significance of participation in steering the process of co-evolution in more globally just ways?

Once you reject the assumption of technology-neutrality, a possibility is indeed opened up for deliberately shaping patent law in such a way that it becomes more tailored to the perceived needs of a specific technology. The only difficulty is that in practice many different actors, often working at cross-purposes, are already trying to influence IP law in their own preferred direction, so that no agency can possibly claim to “orchestrate” the entire co-evolution of SB and IP. The co-evolution of IP law and a specific technology is always part of, and occurs against the background of, a wider process of co-evolution between science and society. Thus the combined rise of classical biotech and an expansionary IP law from 1980 onwards occurred in a neoliberal political context that favored extension and strengthening of IPRs (the IP frame). In its turn, the A2K movement can be seen as a political reaction to the neoliberal agenda of IP expansionism, but is also closely aligned with the rise of information and communication technologies that proved congenial to open-source approaches. More broadly, the modern participatory culture that is celebrated by the A2K movement can also partly be seen as a result of those latter technologies, especially of the possibilities opened up by the Internet (see also Sunder 2012).

The American IP scholars Dan Burk and Mark Lemley, who hold that in practice patent law is always and unavoidably technology-specific, call upon the US courts to explicitly assume the policy role of tailoring the patent law to the specific requirements of innovation in different industries (Burk and Lemley 2003). Standards like non-obviousness (inventive step) and written description and a variety of relevant legal doctrines allow much judicial discretion, which the courts could (and according to Burk and Lemley should) use deliberately as “policy levers” to steer technological innovation in various sectors. Burk and Lemley suggest, for instance, that the courts might raise the bar for non-obviousness with regard to inventions in biotechnology to counteract the proliferation of patents in this area and simultaneously lower it with regard to software inventions (in combination with tightening the requirement for written description) to avoid the notorious mutual overlap between software patents. (They want to limit the scope of software patents, but do not seriously contemplate the possibility of rejecting such patents altogether, although many proponents of free and open-source software would be in favor of such a measure.) Yet there is something deeply paradoxical about their recommendations. US courts are, as Burk and Lemley themselves observe, extremely reluctant to consciously adopt this policy role; they would rather deny that they implicitly play such a policy role at all (although they in fact do so). This means

that the recommendations addressed to the US courts are bound to fall on deaf ears. It also shows that any attempt to orchestrate the co-evolution of IP and SB by seeking to directly leverage the judicial system will probably fail.

The co-evolution of IP and SB has therefore to be put in a broader political context. It is also important to avoid the rather technocratic or legalistic prejudice that patent law simply needs to be tailored to the specific needs of various industries or sectors of technology, as if different groups could not legitimately disagree about what these presumed needs are (witness the opposition to software patents among the open-source movement). Still it is very valuable to point out, as Burk and Lemley have done, that judicial decisions about the patentability of inventions in various technology sectors are inevitably policy-laden.

When we move from the national (US) to the international IP system, the picture becomes even more complicated. Many interested parties (companies, industry organizations, NGOs, scientific researchers, governments of developed and developing countries etc.) are all pushing and pulling in different directions. It is impossible to predict the resultant force and hence the future development of the whole system from this elaborate parallelogram of political forces. We can however turn to a study commissioned by the European Patent Office for an interesting exploration of various scenarios for the future of the global IP system in relation to economic, political and technological developments (EPO 2007). This study may well serve to stimulate our moral and political imagination.

Meanwhile, we should not ignore the fact that the SB community has become an international political factor in its own right through the organization of iGEM competitions between undergraduate students from different parts of the world (Smolke 2009). Despite the strong element of competition, iGEM also teaches the student participants an ethos of sharing and international collaboration by encouraging them to draw from, and submit new DNA constructs to, the Registry of Standardized Biological Parts. The iGEM competitions are also a major mechanism for transmitting the new skills and knowledge of SB to the remote corners of the globe. As Kenneth Oye and Rachel Wellhausen write, “iGEM and other outreach activities of synthetic biologists are models of how to transfer know how by building vibrant international science commons” (Oye and Wellhausen 2009, 138). The participation of Chinese students in the iGEM competitions from 2007 onwards has actually been a unique ‘bottom-up’ route for the emergence of SB in China (Zhang 2011). Familiarity with iGEM practices may also influence attitudes towards patents. We have seen above that the Harvard student team of 2011 attempted to challenge the control over zinc finger technology by a private biotech company. The more young and aspiring SB practitioners imbibe the ethos of sharing as

a routine part of their research practice, the more critical they are likely to become of the proprietary strategies of private companies.

SB pioneer Drew Endy, who is also the main architect of the iGEM competition, envisages the whole endeavour in the broad perspective of a more widespread global participation in SB research for the sake of addressing global health needs. He discerns much promise and potential in the fast progress reached by undergraduate students in successive iGEM competitions: “One net positive impact would be to make accessible methods to produce needed chemicals and materials that are now unavailable or too expensive. More specifically, a reduction in capital and research costs associated with biotechnology research and development would allow a greater diversity of teams to work on many now ignored challenges, such as orphan diseases, that mainly affect poorer people who lack significant purchasing power” (Endy 2011). He contrasts the emerging iGEM practice based on two advances, tools and sharing, with “current biotechnology practice, which... is dominated by hoarding of both materials and property rights”. It is also notable that Endy does not see the poor in the developing world only as passive recipients of the miracle works offered by modern science and technology. Referring to the well-known poster-child of SB, Jay Keasling’s synthetic production of the anti-malaria precursor medicine artemisinin, he asks himself: “What if we could enable thousands of artemisinin projects, each hoping to improve the human condition or our environment? What if we could enable the very people whose livelihoods now depend on intensive and expensive methods of manufacturing and production—such as wormwood tree farming—to help conceive, enable, and benefit from transition to a human civilization that is implicitly and responsibly partnered with the living world?” (Endy 2011). Endy is fully aware that the realization of this dream requires “more than technology alone”, it also requires “supportive legal, institutional, and commercial environments” (ibid.). The outcome of the contest between the IP frame and the A2K frame in the SB field, with its possible repercussions for pharmaceutical innovation, will in all likelihood also be decisive for the realization of this dream.

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