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Defining the Future: Emerging Issues in Biotechnology, Intellectual Property Rights and Technology Transfer

Prabuddha Ganguli, Rita Khanna, and Ben Prickril

1.1
Introduction

Since the formation in 1976 of the first modern biotechnology company, Genentech, the biotechnology industry has grown to become one of the major engines of innovation in virtually all developed economies. Indeed, biotechnology's growth in areas ranging from health, agriculture, environment and industrial processes has been phenomenal. This expansion has been paralleled by mounting public concerns because of potential ethical issues and impact on our health, food and the environment.

The importance of innovation in biotechnology and its widespread applications in health, agriculture and commerce has helped bring issues related to intellectual property (IP) rights and technology transfer into sharp focus. The ongoing global debate on IP rights, especially related to health and agriculture, has hinged on proprietorship of knowledge and its ethical and political implications for innovation, knowledge sharing and technology transfer. The means by which knowledge and technologies are moved from basic research up the value chain to become commercial products is critical to the ability of biotechnological innovation to reach those who need it.

1.2
Historical Evolution of Intellectual Property Regime in Biotechnology

There has been a marked paradigm shift in the field of IP rights itself, especially in the areas of patents and copyrights. The modern patent system originated in 1474 as a means of providing inventors the right to block others from using their inventions in return for registering them with the government.

Early inventions usually dealt with the creation of inanimate and tangible objects, but as understanding of basic phenomena progressed, inventions relating to intangibles became fairly common. The field of biotechnology IP rights is

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often intangible and became even more so when the field was transformed by the advent of molecular biology in the 1960s and 1970s. The tools of molecular biology began to enable production of completely new therapeutic drugs, vaccines, diagnostic tools and plant breeding methods starting at the level of individual genes. The seminal US Supreme Court Case *Diamond v. Chakrabarty* was the turning point in the history of IP rights related to biotechnology. Since the Supreme Court's ruling in *Diamond v. Chakrabarty*, certain non-naturally occurring organisms are eligible for patent protection and the patent system has played a critical role in stimulating an emerging biotechnology industry. This decision led the way to patenting life forms provided they were created by human intervention, and met the requisite criteria of novelty, inventive step and utility. Patent exclusivity for biotechnology inventions catalyzed further investments in R&D in biotechnology and marked the dawn of a new biotechnology industry. The tremendous development of this industry and the concomitant increase in the proprietorship of knowledge through IP rights has raised contentious issues in knowledge transactions in a competitive environment.

1.3 Issue of Patentability of Gene Sequences, Antibodies, Early-Stage Technology/Platform and 'Insufficient Support for Claims'

The growth of biotechnology has presented new challenges to the patent system. As noted above, right from the outset issues of what is patentable and how it should be patented have been particularly important and contentious in the biotechnology field. Some aspects have been clarified and resolved, while others still remain to be addressed and new issues continue to emerge. This section will review the history and remaining issues with respect to the patentability of genes, antibodies, research tools and platform technologies.

A subject in biotechnology that has attracted critical attention is the subject matter of erythropoietin. A 2004 UK House of Lords Decision invalidating Kirin–Amgen's erythropoietin patent questioned the patentability of gene sequences as the court observed that 'gene sequences are to be assessed as ''discoveries'' or just ''information about the natural world'''. This decision suggests that the bar to patentability in matters related to gene sequences needs to be regularly reassessed.[1)]

The patentability of antibodies has also been questioned in several recent decisions as in *Noelle v. Lederman* [355 F.3d 1343, 1349 (Fed. Cir. 2004)] and *Smithkline Beecham v. Apotex* [403 F.3d 1328 (Fed. Cir. 2005)]. In the case of *Noelle v. Lederman*, the court observed that the written description of the specification did not provide sufficient support for claims to a human antibody because it failed to disclose the structural elements of the human antibody or antigen. In the *Smith-*

1) Crespi, R.S. (2005) Erythropoietin in the UK: a setback for gene patents? *Nature Biotechnology*, **23**, 367–8.

kline Beecham v. Apotex matter, the court observed that there was 'inherent anticipation'.[2)]

The ongoing case of *Novartis Pharmaceuticals Corp. v. Teva Pharmaceuticals USA, Inc.* [05-1887, 2007 WL 2669338 (DNJ 6 September 2007)][3)], addressing issues related to obviousness, provides insight regarding the importance of references that teach away from an invention. The question being addressed is whether a specific article teaches away from penciclovir, but the prior art 'as a whole' did not teach away from using penciclovir as a lead compound.

Patenting of early-stage technologies such as target identification, pathway analysis, platform technology development and even generation of putative biotherapeutic compound leads have also been subject to debate. In several cases that have come before the courts especially in the United States, such as *The University of California v. Eli Lilly* [119 F.3d 1559, 43 USPQ2d (BNA) Fed. Cir. 1997), cert. denied 523 US1089 (1998)], *Amgen v. Chugai* [927 F.2d 1200, 18 USPQ2d (BNA) 1016 (Fed. Cir. 1991)] and *Fiers v. Revel* [984 F.2d 1164, 25 USPQ2d (BNA) 1061 (Fed. Cir. 1993)], it has been clearly shown that when such patents are challenged, they have not stood the test of validity regarding an adequate written description of the invention.[4)]

The field of genomic diagnostics and IP rights is also becoming embroiled in controversy. Most debates have centered around the patents on *BRCA1* and *BRCA2*, questioning the intent of the patent holders to unreasonably restrict access to the important diagnostic tests. In an article titled 'Emerging patent issues in genomic diagnostics',[5)] Barton raises several questions especially on the problem of royalty stacking. There could be a series of patents claiming the use of a specific gene sequence to identify a specific biological property that may make it difficult for the integrator of a microarray/chip device to assemble the rights to use the different patented sequences that are relevant to the clinical or research application. In principle, each holder of a patent on a diagnostic sequence marker used in the array could traditionally block marketing or the use of the array. Similarly, patents may be issued on sequences that might identify drug efficacy or side-effects. Such patents may cover sequences as biomarkers of an effect on drug metabolism, or the use of sequences to make decisions about drug regimes. Barton suggests that the patent law needs to be assessed keeping in mind such developments in the field of biotechnology and to improve access to the pool of available knowledge.

Another issue that is gaining prominence is the question of 'patenting race'. An article by Khan[6)] raises issues related to the strategic use of race as a genetic category to obtain patent protection and drug approval as they are increasingly

2) Lu, D.L., Collinson, A.M. and Kowalski, T.J. (2005) The patentability of antibodies in the United States, *Nature Biotechnology*, **23**, 1079–80.
3) Lu, D.L., Collission, A.M. and Kowalski, T.J. (2007) Patentability issues surrounding antivirals, *Nature Biotechnology*, **25**, 1403–4.
4) Suster, M.J., Su, H. and Blaug, S. (2003) Protecting rights to early-stage technology, *Nature Biotechnology*, **21**, 701–3.
5) Barton, J.H. (2006) Emerging patent issues in genomic diagnostics, *Nature Biotechnology*, **24**, 939–1.
6) Kahn, J. (2006) Patenting race, *Nature Biotechnology*, **24**, 1349–51.

being evoked in biotechnology patents. Between 1976 and 1977 there were no issued patents in the United States that mentioned racial and ethnic categories. However, during the period 1998–2005, there were a total of 12 instances in issued patents in which race and ethnic categories were mentioned. Further, in patent applications from 2001 to 2006, there were 65 instances in which race and ethnic categories were mentioned. In June 2005, BiDil became the first drug approved by the US Food and Drug Administration (FDA) with a race-specific indication. Underlying BiDil's New Drug Application for FDA approval is a 2002 race-specific patent specifying use of the drug for treatment of heart failure in an African-American patient (US 6465463). Interestingly NitroMed, BiDil's corporate sponsor, also holds an earlier patent (US 4868179) to use BiDil in a general population, regardless of race. The earlier patent expired in 2007, whereas the race specific patent expires in 2020.

Similarly in Europe, in June 2005, the European Patent Office upheld a patent owned by Myraid Genetics relating to the testing for *BRCA2* genetic mutation for 'diagnosing a predisposition to breast cancer in Ashkenazi Jewish Women'.[7] Such patents will have profound sociological and economic consequences in due course.

1.4 Scope of Patent Claims

As in other areas of IP rights, the appropriate term, breadth and specificity of patents has been a continuing and, indeed, a growing concern. The number of patents issued has grown exponentially. Proponents of more stringent IP rights have stressed the importance of a robust system of patents for biotechnology. On the other hand, many have raised concerns about the excessive number and breadth of patents, and their growing complexity of knowledge sequestration is discouraging efficient diffusion of knowledge and undermining research. Striking a balance between adequate IP rights protection and the efficient availability of knowledge with spillover effects remains a continuing challenge.

Patenting of research tools has been at the center of an important debate over the last decade, without much clarity of date. These tools are generally recognized as embracing the full range of resources that scientists use in the laboratory, including such items as cell lines, animal models and reagents.[8]

Several areas such as patenting of expressed sequence tags (ESTs), which are essentially research tools, have been perceived to severely restrict research, while being unlikely to result in discrete commercial products. One means of addressing these concerns has been to raise the bar to utility, as was done through the

7) Kienzien, G. (2005) *The Scientist*, **July 1**, http://www.the-scientist.com/article/display/22719.

8) NIH (1998) *Report of the NIH Working Group on Research Tools*, June 4, NIH, Bethesda, MD. Available at http://www.nih.gov/news/researchtools/.

Utility Examination Guidelines set forth by the US Patent and Trademark Office (PTO) in January 2001. The case in question that issues in EST patenting is well discussed in an article by Davis *et al.*[9] The article elaborates on Ficher's claims in which Monsanto scientists in their patent application disclosed approximately 32 000 specific nucleotide sequences for ESTs of various maize tissues. Although, during the patent prosecution, the PTO restricted Monsanto to five ESTs, the patent claim read 'A substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO:1 through SEQ ID NO:5'. Such a claim effectively covers any purified nucleic acid that includes one of the five ESTs so long as the nucleic acid (not necessarily its EST portion) encodes a maize protein or even a fragment of a maize protein. The question raised with such broadly granted claims is whether they would prevent basic genomic research or deny the use of associated proteins as targets for product screening.

'Reach-through' claims to drug targets have a major impact on ownership and, therefore, control on future activities involving drug targets, and have been the subject of much debate. In several cases, if a variant has less side-effects or is more effective, the first patent with 'reach-through' claims could preclude the development of drugs for the variant target forms. Under such circumstances, there are varying opinions on the options that can be exercised, one of them being that the holder of patent rights has a strong incentive to negotiate licenses to subsequent drug developers or to variations in the metabolic pathways that breakdown the drug.[10]

Patenting in areas related to stem cells, especially in terms of claiming proprietary rights to 'pluripotency', is opening up new challenges to the drafting of patent specifications in terms of what would be considered as adequate disclosures, allowable and enforceable claims construction, and examination processes in patent offices and further the framing of national policies.

Recent proceedings in the PTO *vis-à-vis* the rejection, re-examination and allowance of patents especially related to US 5843780 (claiming pluripotent primate embryonic stem cells and a method of isolating a primate embryonic stem cell line), US 6200806 (claiming pluripotent human embryonic stem cells and a method of isolating a human embryonic stem cell line), US 7029913 (claiming pluripotent human embryonic stem cells) and rejection of the continuation application US 20050158854 (claiming pluripotent human stem cells) are of relevance as they provide directional indications on future approaches likely to be taken by patent offices, especially in the United States, to arrive at conclusions on 'obviousness' and 'enablement requirements'.[11] The key questions that have

9) Davis, P.K., Kelley, J.J., Caltrider, S.P. and Heining, S.J. (2005) ESTs stumble at the utility threshold, *Nature Biotechnology*, **23**, 1227–9.

10) Bohrer, R.A. (2008) Reach-through claims for drug target patents: Rx for pharmaceutical policy, *Nature Biotechnology*, **26**, 55–6.

11) Vrtovec, K.T. and Scott, C.T. (2008) Patenting pluripotence: the next battle for stem cell intellectual property, *Nature Biotechnology*, **26**, 393–5.

surfaced with regard to the granted patents US 6200806 and US 7029913 at the re-examination stage relate to 'whether methods described in the prior art would extend to the method of isolation of embryonic stem cells?' and 'whether the techniques used were unpredictable and not universally applicable to the isolation of embryonic stem cells from other species, particularly human'. Similarly, while rejecting the claims of the continuation application US 20050158854, the argument by the PTO has been 'because the specification, although being enabling for the preparation of pluripotent hES [human embryonic stem] cells, does not reasonably provide enablement for a preparation of pluripotent hES cell'. Further the question that needs resolution is whether the term 'pluripotent hES cells' cover 'human iPS [induced pluripotent stem] cells'. The answer to this question would be based on the definition of these terms which hopefully will get clarified by courts in future.

The matter is of immense interest in view of the patent application by Yamanaka (WO/2007/069666 published on 21 June 2007). This patent discloses a means for inducing the reprogramming of a differentiated cell without using any embryo or embryonic stem cell, thereby establishing an inducible pluripotent stem cell having similar pluripotency and growing ability to those of an embryonic stem cell with good reproductivity. This is accomplished by a nuclear reprogramming factor for a somatic cell comprising products of the following three genes: an *Oct* family gene, a *Klf* family gene and an *Myc* family gene. The Japanese Patent Office has recently granted the patent 2008-131577 in Japan, keeping a lead in the induced pluripotent stem cell patent race.[12)]

Two recent examples illustrate tensions among various stakeholders involved in the commercialization of such developed technologies.

Monsanto Technology LLC v. Cargill International SA and Cargill PLC [Neutral Citation Number: [2007] EWHC 2257 (Pat) Case No: HC06C00585; http://www.bailii.org/ew/cases/EWHC/Patents/2007/2257.html], a litigation in the United Kingdom, serves as an example of how construction of DNA-based claims could be interpreted in terms of the specificity or breadth of the claims. Monsanto sued Cargill for importing into the United Kingdom soya meal produced in Argentina alleged to be derived from soya beans modified to contain a gene conferring resistance to a herbicide called glyphosate (Roundup). Cargill counterclaimed for invalidity of the Monsanto patent and also contested infringement. The judge found the patent valid as amended by Monsanto, but not infringed by Cargill's importation of the soya meal.

Claim 1 of the EP (UK) 0546090 states:

An *isolated* DNA sequence encoding a Class II EPSPS [5-enolpyruvylshikimate-3-phosphate synthase] enzyme, said enzyme being an EPSPS enzyme having a K_m for phosphoenylpyruvate (PEP) between 1–150 μM and a K_i(glyphosate)/K_m(PEP) ratio between 3–500, which enzyme is capable of reacting with antibodies raised

12) Cyranoski, D. (2008) Japan fast-bracks stem-cell patent, *Nature*, **455**, 269.

against a class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO: 3 and SEQ ID NO: 5, *which DNA sequence encodes the amino acid sequence of SEQ ID NO: 3 save that serine at position 2 is replaced by leucine*.

The judge agreed with the interpretation that the term 'isolated' when read in the context of the invention disclosed in the patent described the creation of transgenic plants that were resistant to glyphosate and in order to achieve that aim, the gene sequences in question should be purified and available for manipulation for use in the processes claimed in the patent. The judge found that Monsanto had not (i) completed experiments to demonstrate that all of the test criteria set out in Cargill's construction had been met, or (ii) proved that the DNA that was actually present in the soya meal was 'isolated', thereby resulting in the finding that Cargill did not infringe the DNA product claims of the said patent.[13)]

This decision highlights the manner in which patent claims may be interpreted narrowly without allowing broad interpretation of terms used in the claims, and further suggesting that claims to the production of a genetically modified organism may not be 'proximal' enough to derivative products to be deployed to prevent their importation.

It has now been well documented that there has been gradual decline in the filing and granting of patents claiming DNA sequences. However, patent offices have been granting patents claiming DNA with narrower scope and relatively robust claims especially claiming splice variants and single nucleotide polymorphisms.[14)]

1.5
Institutional Arrangements for Technology Transfer

A policy concern that arose early in the drug development field was how to create adequate incentives for commercialization of results of basic research. In a system where basic research was primarily being undertaken by academic and public institutions, there was a concern that this research was neither being utilized nor producing adequate returns for the taxpayer. One important manifestation of this concern relates to the lack of incentives for the development of medicines for developing country diseases. Although most governments have instituted departments to fund and administer R&D the issue of IP rights and technology transfer between institutions remains a major bottleneck. New mechanisms (i.e. public–private partnerships) is to develop and manage IP are beginning to have a positive impact for a large number of people in developing countries to meet their need for better access to food and medicines.

13) Cohen, S. and Morgan, G. (2008) Monsanto Technology LLC v. Cargill: a matter of construction, *Nature Biotechnology*, **26**, 289–91.

14) Hopkins, M.M., Mahdi, S., Patel, P. and Thomas, S.M. (2007) DNA patenting: the end of an era? *Nature Biotechnology*, **25**, 185–7.

An example of intra-institutional collaboration is the establishment of the Oxford Genetics Knowledge Park (OGKP) in 2002, which was a partnership between Oxford University and the Oxford Radcliffe Hospitals NHS Trust funded by the UK Department of Health/Department of Trade and Industry with the aim of translating advances in genetics research into clinical practice. Important issues identified by the OGKP for effective working are research exemptions and their applicability, landscaping of patents to minimize risk of infringement, and need for infrastructure for support.[15] There are several examples of technology development and transfer by and between institutions.[16]

Easy access to proprietary information is of significance to researchers especially in universities to reduce their risks for patent infringement. Several resources such as the Public Intellectual Property Resource for Agriculture (www.pipra.org), CAMBIA (www.cambia.org) and several other organizations are focusing their efforts to promote an open forum to assist in IP rights-related matters especially for researchers in universities.[17]

The 'Cooperative Research and Technology Enhancement Act of 2004' (CREATE ACT) became effective in September 2005 in the United States, and is intended to promote collaboration among industry collaborators, and therefore promote innovation, decrease costs, and ultimately enable the commercialization of patented biotech products and processes for societal good. This Act will have major implications on technology transfer and IP rights in areas related to biotechnology. However, to make the CREATE ACT meaningful, it will be important to address issues related to 'research exemptions' and diagnostic tools, and to ensure freedom of researchers to use patentable inventions for their research.[18]

1.6 Policy Issues and Challenges

Technology transfer in biotechnology depends on the transformation of basic research findings into commercial products and requires a strong IP rights system to succeed. Along the path, there are a host of issues that need to be addressed. These include:

- Knowledge 'sequestration' caused by proliferation of biotechnology patents, thereby placing knowledge into privatized 'knowledge black holes' and patent thickets, therefore making it accessible to others.

15) Kate, P., Hawkins, N. and Taylor, J. (2007) Patents and translational research in genomics. *Nature Biotechnology*, **25**, 739–41.

16) Ganguli, P. (Guest ed.) (2005) Special volume 'Technology Transfer with IPR', *Journal of Intellectual Property Rights*, **10**, 349–456.

17) Yancy, A. and Stewart, C.N. Jr (2007) Are university researchers at risk for patent infringement? *Nature Biotechnology*, **25**, 1225–8.

18) Mills, A.E., Chen, D.T., Gillon, J.J. Jr and Tereskerz, P.M. (2006) The CREATE Act: increasing costs associated with the biotech industry? *Nature Biotechnology*, **24**, 785–6.

- Instances of abusive monopoly resulting in higher prices for patented medicines and other products.
- Granting of broad claims by various patent offices leading to excessive patent protection.
- Freedom to operate restrictions on academic researchers due to patenting of research tools and issues related to non-clarity on 'research exemptions' undermining scientific progress.
- Increasing complexity of licensing deals resulting in increased research and transaction costs, including litigation.
- Privatization of patents from government-funded R&D by universities and research institutions, especially where little benefit accrues to the general public.

Countering these concerns, proponents of a strong IP rights regime argue that without adequate IP rights protection, transfer of technologies would be stymied, and investments in R&D would not yield meaningful returns due to negative impacts on both the potential for further investments and on innovation and knowledge diffusion to the detriment of society. Proponents also suggest that a strong IP rights system would promote effective and appropriate technology transfer and the development of human resources in lesser-developed countries lacking the critical mass of expertise and infrastructure in biotechnology.

Frameworks of IP rights clearly need to keep pace with the rapid developments in science and technology in order to create an enabling platform for legitimate access to information. Sharing and using knowledge equitably benefits all stake holders and promotes the sustainable growth of the global society. In the same way, IP rights issues that impact on human rights or raise ethical concerns need to be analyzed systematically and take into account the concerns in national and international policy affecting technology transfer in biotechnology.

An Organization for Economic Cooperation and Development (OECD) report[19] exhaustively addresses the issues related to genetic inventions, IP rights and licensing practices. Some of the key conclusions of the OECD report are:

- *Responsibility of the patent offices*. The scope of patent claims in relation to biological and genetic material continues to be a matter of concern. For example, broad claims in several cases have been allowed by patent offices so as to give rights to the patent applicant on the genetic makeup of plants and organisms beyond individual varieties, species and genera to incorporate key elements of genomes across classes, which in effect cover species that have not been invented or even known. Patent offices should, therefore, issue clear guidelines on benchmarks for patentability ('raising the bar') so that examiners do not issue patents wrongly or allow exceptionally broad claims.
- *Need for public engagement*. Enhancing awareness and engaging the public in debates on applications of biotechnology, patenting, technology transfer, etc.,

19) Organization for Economic Cooperation and Development (2002) *OECD Report of the Workshop on Genetic Inventions, Intellectual Property Rights and Licencing Practices, 24 and 25 January*, OECD, Berlin, Germany. Available at http://www.oecd.org/dataoecd/7/42/194903.pdf.

will be crucial if public trust in the patent system and its application to biotechnology is to be strengthened.

- *Institutional arrangements for the promotion of technology transfer.* Policies dealing with biotechnology, IP rights and technology transfer in academia and industry need to be aligned that academia using public funding is not hindered in making use of patented inventions without liability. In this regard, governments should harmonize their policies on the subject of 'research exemptions' so that there is some uniformity in interpretations in diverse jurisdictions.
- *Governmental policies.* Objective monitoring of patenting and licensing of genetic inventions should become the basis for policy making to ensure fair and reasonable access to genetic information and subject matter of patented inventions.
- *Anti-competitve practices.* Guidelines for the use of provisions by governments on issues related to anti-competitive practices in contractual licenses, effective use of competition law to control abusive exploitation of IP rights, benchmarks for the issuance of compulsory licenses need to be defined more clearly so that IP rights are used with fair benefit sharing between the diverse stake holders in the interest of societal growth.

It must be recognized that the patent system was set up to stimulate innovations. The idea was that a patent would give the inventor rights to their invention in return for disclosing it so that others who would have access to the knowledge would be able to invent around or contribute through improvements. However, in the case of biotechnology, and especially in systems biotechnology, allowing inventions related to basic biological processes often leaves no options for other inventors to invent around, thereby giving a virtual monopoly to the patent holder of the basic patent. This raises serious questions about the granting of patents for basic processes in biology, which seemingly conflicts with the very purpose of granting of patents. There is a growing feeling that IP rights in biotechnology are possibly indirectly denying the public at large some of the biomedical and agricultural benefits that they rightly deserve as a part of the social contract between the inventors and the society.

The Bayh–Dole Act in the United States allowed universities to own their government funded inventions and license them to commercial partners. However, universities are increasingly under pressure to sign contracts with restrictive non-disclosure agreements for their privately funded research, causing undue delays in the timely sharing of their findings with their peer groups. A movement of 'Creative Commons' is also gaining momentum with an increasing concern on establishing a research exemption from infringement of gene-related patents. With lessons learnt from the experiences of implementing the Bayh–Dole Act in the United States, similar legislations are under active consideration in several countries.

It has been reported that 20% of the human genome is claimed as patents, of which two-thirds are owned by private firms. Some of these patents appear to have been granted with broad claims that are in themselves questionable due to the limited ability of patentees to satisfy the utility (industrial applicability)

requirement for their invention. The creation of strategic patent estates by private firms using such patents is now being seriously questioned on the basis that they are leading to a virtual monopoly and underuse of the developed knowledge for the social good.

Further, as genetic testing moves into mainstream medicine, the effect of gene patents will have far-reaching effects on the healthcare system and the industry servicing it, and therefore will have to be handled with care.[20]

Patent filing in the area of stem cells is on a steady growth path, and recent patents granted to Wisconsin Research Foundation and Kyoto University research groups have become very controversial.[21] The emergence of patent thickets is likely to cause problems in 'freedom to operate', imposing multiple layers of transaction costs and stacking of royalty payments beyond levels that can be supported by the value of single innovations. Fears have been expressed about the possibility of slower movements of innovations to the market place, dampening investor of confidence, and the undermining the transfer of technology and networking to promote public–private partnerships. The need to establish institutionalized models for collective networking involving 'technology development conglomerates', 'consortia technology development programmes with appropriate process for IP ownerships and equitable benefit sharing among participating partners', open-source licensing, formation of patent pools and IP rights warehousing including clearing mechanisms will pave the way for the development of technologies, making their benefits accessible to society in a cost-effective and affordable manner. Caution is to be exercised while performing in such collective modes in order not to form coercive groups and promote anti-competitive frameworks.

The impact of some recent US Supreme Court decisions on license negotiations, finality of licensing agreements, and control by licensors can exert a detrimental impact on the downstream use of their licensed technologies and, therefore needs to be appreciated with special reference to cases such as *eBay, Inc. v. MercExchange LLC, MedImmune, Inc. v. Genentech, Inc.* and *Quanta Computer, Inc. v. LG Electronics* as they will begin to shape the cooperative trajectories of the future.[22]

The convergence of nanotechnology, biotechnology, information technologies and microelectronics has opened up new opportunities in areas as diverse as drug delivery systems, tailored tissue engineering, microfabrication, biosensing devices and microarray technology. The development of these new functions will require a high level of expertise and sophistication in the management and transfer of technology. Both developed and developing countries need to ensure that their IP regimes and technology transfer mechanisms are able to keep pace with these developments.

20) Klein, R.D. (2007) Gene patents and genetic testing in the United States, *Nature Biotechnology*, **25**, 989–90.

21) Bergman, K. and Graff, G.D. (2007) The global stem cell patent landscape: implications for efficient technology transfer and commercial development, *Nature Biotechnology*, **25**, 419–24.

22) Giordano-Coltart, J. and Calkins, C.W. (2008) Recent Supreme Court decisions and licencing power, *Nature Biotechnology*, **26**, 183–5.

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