THE IMPACT OF PATENTING RESEARCH TOOLS ON RESEARCH ACTIVITIES

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Abstract

Historically, intellectual property (IP) protection focused on research outputs rather than inputs, and access to scientific knowledge was assured through the limitation of the subject matter. Recently, there has been a clear tendency to shift the focus of IP to the inputs themselves especially in some technology fields such as biotechnology. This is illustrated by extensive patenting of research tools that traditionally have been in the public domain.

This paper focuses on the impact of patenting of the research tools on research activities in general and on public R&D in the fields of public health and agriculture in particular. The main conclusion of the research is that there is at present a tendency to move beyond the protection of innovative and creative activities towards protection of economic ones sometimes at the expense of the former. Hence, it was recommended that developing countries should on the one hand re-assess their role in the ongoing global IP negotiations (from mere spectators to effective players) so as to protect their vital interests through access to scientific knowledge, and on the other adopt specific policies to mitigate adverse impacts especially by tougher application of the statutory research or experimental use exemption

ملخص:

أدت العولمة إلى الاعتماد المتزايد على رأس المال الفكري كوسيلة أساسية للتنافسية على المستويين المحلي والعالمي. ونظرا لهيمنة الدول المتطورة وخاصة منها الولايات المتحدة الأمريكية على مخزون وتدفق التكنولوجيات الحديثة فإنها عملت ولا تزال تعمل على دعم هذه الهيمنة عن طريق فرض نظام عالمي موحد لحماية الملكية الفكرية وتوسيع مجاله ليشمل ما يسمى بأدوات البحث. ومن المتوقع حسب المختصين في مجال حقوق الملكية الفكرية إلى حرمان مراكز البحث العلمي والتكنولوجي في الدول النامية من إمكانية الاستفادة من هذه الأدوات نظرا لتحولها من سلعة عمومية إلى سلعة خاصة.

تتناول هذه الورقة أهم العوامل التي أدت إلى توسيع مجال حماية الملكية الفكرية لتشمل أدوات البحث العلمي والتكنولوجي وكذا آثار ذلك على القطاعات الحيوية للنشاط الاجتماعي كالزراعة والصحة في الدول النامية بشكل عام والعربية منها خاصة. كما يقدم البحث بعض المقترحات العملية التي يمكن لمتخذي القرار في الدول النامية الأخذ بها عند رسم سياساتها المحلية والجهوية لتخفيف تلك الآثار السلبية.

Introduction

Most researchers are of the view that the TRIPS Agreement has represented a major shift in international IPR protection rule making by limiting WTO members discretion with respect to the use of IP as a tool for the promotion of innovation. The main characteristics of this development are: increasing privatization of knowledge and the corresponding shrinkage of the public domain. Nowadays IPR protection covers products and processes in all sectors including pharmaceuticals, food industry and agriculture as well as restrictions on copyright exceptions. More recently, the trend to privatize knowledge has even more increased through TRIPS-plus clauses included in bilateral and regional trade and investment agreements as well as through recent WIPO initiatives aimed at IPR harmonization .

In concrete terms, this trend can be illustrated through the study of the object of IP protection. Historically, IPR focused on the protection of research activities output rather than inputs. At present, there is a strong tendency to shift the focus of IPR protection to the inputs themselves. This development can be shown through: a) protection of secondary databases; b) patenting of research tools (scientific knowledge that used to be in the public domain; and c) rules on data exclusivity.

Our focus in this paper will be on the impact of patenting of research tools (PRT) on research activities in general and on public R&D in the fields of public health and agriculture in developing countries in particular. Preliminary results of research on the subject show that this IPR trend in developed countries has resulted not only in increased litigation and costs but also in slower pace of research and increased secrecy. Our conclusion is that patenting public research institutions results might boomerang by creating costly and complicated exchange barriers to research tools among these institutions, and hence further weakening their capacities to participate in world knowledge creation.

IMPLICATIONS OF PRT ON RESEARCH ACTIVITIES

There are a number of obstacles that may result from the patenting of research tools; the most important ones are:

1- Increased research and transactional costs: even where patent holders are amenable to licensing, the price demanded may be a barrier to researchers. Moreover, negotiations can be long and complex, thus imposing delays and management burdens on research.

The terms of licenses or Material Transfer Agreements (MTAs) can be such that they make collaboration and communication with other researchers more difficult. The Du Pont Cre-lox case is the example. Furthermore, research institutions sometimes find themselves confronted with the so-called "patent thickets and royalty stacking". The term "patent thicket" has been coined to characterize a technological field where multiple rights owned by multiple actors may impede R&D because of the difficulty and cost of assembling the necessary rights. The patent thicket is a major problem because useful innovations in many technology fields require multiple inventive steps and technologies. Patent thickets characterize a number of technological fields especially telecommunications, semiconductors, high density polymers and recently biotechnology. Multiple claims make sorting out license obligations time consuming and costly, and sometimes even impossible. Thus, it was reported that when the public sector researchers in Switzerland and Germany developing Vitamin-A enriched rice, went to check the legal status of their discovery, they found that they could be infringing a minimum of 70 and possibly over 100 patents. The accumulation of royalty agreements necessary to develop end products may reduce a firm s profits to a point where pursuing commercialization is no longer viable, thus leading to a 'royalty stacking' problem. "Industry representatives acknowledged royalty stacking as an ongoing concern…." [i]

2- Increase in secrecy and slower pace of research: in the biomedical science for example there is ample evidence that research delays are increasing. The withholding of results, research materials and data is reputed to be more common in genetics than in other fields. Delays in diffusing and sharing data and results with other researchers are often attributed to requests by commercial partners. They may also be used to establish a scientific lead. The effect of increased secrecy might slow the pace of research by making it impossible to verify results and by increasing duplicate research activities.

3- Blocking research activities in certain fields: patents on early fundamental discoveries (especially scientific building blocks) may discourage or limit their use and hence slow the pace of research in that field. The most widely quoted example is the Cohen-Boyer patent on recombinant DNA. Many researchers fear that patents granted on genes implicated in disease could have such a blocking

effect on further research by others on the same disease. In the words of a recent USPTO paper:

"Many feel that by allowing genetic information to be patented, researchers will no longer have free access to the information and materials necessary to perform biological research. This issue of access to research tools relates to ability of a patent holder to exclude others from using the material. Further, if a single patent holder has a proprietary position on a large number of nucleic acids, they may be in a position to "hold hostage" future R&D efforts".[ii]

4- Reach-through claims: they are claims made in a patent or licence to the ownership of future inventions based on disclosed inventions. These are rights to potential future inventions made by the user of the patented or licenses research tools. Thus, providers of research tools may seek royalties on future product sales, outright ownership of future inventions or option to acquire exclusive or non-exclusive licenses on future patents. Reach-through claims are also common in MTAs that do not usually require payments at the time of the transfer. Most MTAs allows the provider to obtain payments upon the sale of, developments that the recipient makes with the materials provided, or either own or license exclusively. Many observers consider these claims undesirable as they burden all the developments achieved after the use of the material, license, or patent, as well because they are seen as providing an unfairly high level of compensation to the provider.

For these reasons, US firms like German and British ones, tend to avoid research projects for which there are many existing patents on research tools. The "tragedy of the anti-commons",[iii] a term used by Heller and Eisenberg, refers to the situation where there is a large number of patent holders over the building blocks necessary for research. The proliferation of patents in certain fields such as bio-medical and genetics could lead to such a tragedy, making it difficult for researchers to pool licenses on all that is needed to accomplish their projects. The access problems blend into one another and the resulting barriers to further research and innovation are similar, whether it is a single broad patent on a research tool or many contributing research tools, or whether it is a single owner' refusal to license or the transaction costs of negotiating with many patentees. American academic scientists reported problems of access to important technology fields as early as 1996. The most important barriers they cited are refusals by patentees to license, a

problem that emerged as a consequence of the dominance of the private sector in new technology fields. Even public institutions responding to new attributed incentives, do not always promote access. These simple refusals shade into the more complicated problem of the patent thicket described above. "Sometimes the shutting out of researchers from a technology or line of inquiry is less direct but no less effective".[iv]

Although academic researchers may be more vulnerable than their colleagues in the private sector to access barriers, yet as Heller and Eisenberg, "the tragedy of the anti-commons" applies to all. Thus in reaction to the patent thicket, firms has developed a number of strategies such as "defensive patenting" and other cooperative actions including pooling and cross licensing. " Recently, firms often attempt to protect themselves against infringement suits by acquiring patent portfolios (frequently on very minor inventions) of their own, so that they can deter litigation through the threat of reciprocal suit…….Building the portfolio requires enormous legal cost but contributes little to research incentives".[v] Cooperative responses have also been attempted in some technology fields, but these also have their costs. This may explains why there is intensive activity of acquisitions and mergers in these fields. Indeed, many observers believe that recent extensive merger and acquisition activity in biotech industry is driven at least in part by the need to ensure the freedom to operate. Very recently, some public research institutions- both national and international and in developed as well as in a few developing countries are practicing "defensive patenting" as a bargaining chip.

REASONS BEHIND RECENT SURGE IN PATENTING

Although economists who have studied the phenomenon are not in complete agreement about the causes of the patenting surge, but most explain that essentially by the policy changes since the early1980s.There are many reasons why patents are being more frequently acquired and aggressively asserted and enforced. The main ones are:

1- The increasing national and global competitiveness has forced firms to exploit new ways of protecting market position, particularly since economic regulation, trade barriers, and national monopolies have been considerably reduced. An example of this is the telecommunications industry. In many cases patenting activity has departed from its traditional role (to increase the incentive to invent) and has become strategic. Thus, for example, it was reported that an increasing number of firms in biotechnology industry attempt to

acquire patent portfolios of their own so as to protect themselves against litigation as well as to improve their bargaining position in cross-licensing negotiations.

2- The increasing importance of knowledge-based economic activity particularly in developed countries. Between 1980 and 1994 the share of global trade involving high-tech (incorporating intellectual property) production rose from 12 to 24%, and by the end of the 1990s accounted for more than 50% of the GDP of OECD countries.[vi]

3- Cost recovery of research expenditure through licensing. In 1990, total revenues from patent licences amounted to $15 billion. By 1998, licensing fees garnered $100 billion and some analysts predict revenues of more than half trillion dollars per annum by 2006.[vii]

4- The ever extending scope of patenting: An important factor in the surge in patenting in recent years has been the extension of the IP system to virtually all processes and products and to all WTO member countries as well as public institutions including universities. As a result of these parallel evolutions, the distinction between the private and the public domain of knowledge has blurred. IPR , formerly restricted to privately funded research, today protects publicly funded research results. Thus public scientific activity is moving slowly but surely in the same direction as the private one. Some Governments have approved laws facilitating the private appropriation of knowledge, previously considered in the public domain. The Bayh Dole Act in the US, and similar laws in other developed countries and even some developing countries, have authorized universities and other public research institutions to patent and license what is used to be in the public domain. For example, from the years 1981-1985, 1887 USA patents were awarded to inventors who assigned their rights to entities containing the word "university" in its name, comprising only 0.59% of total USA patents during these years. From 1996 to 2000, this number increased to 13940 or 2.15% of total patents awarded.[viii]

Non-profit research institutions also rely substantially on funding from the private commercial sector. This money is often encumbered with IPR constraints, such as an obligation to license or assign resulting inventions back to the funding institution.

5- "Vigorous" enforcement of IPR: This is especially the case in the United States where according to many analysts; the system is biased in favor of patent applicants and holders. Indeed some observers consider the creation of the Federal Circuit court as the most important decision that has been taken in the field of the IPR since the early 1980s. This is so as it resulted in higher rates at which patent validity and patent holders prevailed in litigation. In an analysis for the Senate Judiciary Committee, the U.S. General Accounting Office reported in 2001 that two-thirds of state universities received accusations of infringement, often in the form of cease-and-desist letters. Even public research institutions have recently been subject to patent infringement litigation. Thus, the Federal Circuit Court, ruling on a claim of a common law "research exemption" from patent infringement liability in a case brought against Duke University in October 2002, decided that "research solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry is protected" from patent infringement,[ix] but it held that the protection does not extend to organized research activity pursued as part of the legitimate business of an institution, whether nonprofit or for-profit. A few months later, the Supreme Court declined to hear Duke University's appeal, thus allowing the decision to stand.

Although it is difficult to anticipate this decision's consequences, an informal poll of public research institutions reported to a September 30, 2003 forum organized by the Association of American Universities revealed that a number of public research institutions were receiving more notification letters with patent infringement in the aftermath of the decision. "Almost certainly, the number of complaints and conceivably the number of lawsuits will increase in the aftermath of the Madey v. Duke ruling that universities in general may not claim a research exemption defense under common law". [x]

Other observers have suggested that the USPTO very frequently issues patents for inventions that do not conform to generally accepted patentability standards especially in technology areas that are newly patentable such as software, genomics and biotechnology in general. "Over the past decade the quality of issued patents has come under sharp attack".[xi]

CONSEQUENCES OF PATENTING RESEARCH TOOLS ON PUBLIC HEALTH AND AGRICULTURE

Our focus in this section will be on biotechnology due to the fact that recent technological development in these two sectors relies essentially on inventions made in the biotechnology field. Issues of access to research tools in biotechnology have become a major concern in developed countries especially in the USA. Biotechnology research tools include genomics data bases, DNA chips, recombinant DNA technology, genes and receptors, PCR, combinatorial libraries and even transgenic mice and other animals. This list shows that a good proportion of entire range of biotechnology can fall under the term "research tools". Furthermore, there are examples of broad patents on targets with specific therapeutic and diagnostic functions being licensed exclusively; and complaints about exclusion from using these targets in R&D are increasing. The main examples are: the CCR5 and the NF-Kb messenger protein.[xii] Biotechnology is the field most affected by the patent thicket. The increasing number of patents, increasing patent scope, and granting of patents on more fundamental discoveries have created a patent thicket, and consequently impede further research and commercial development, since useful innovation requires multiple inventive steps and technologies. The use of modern biotechnology to develop, for example a genetically modified crop, requires use of multiple research tools, including transformation tools, gene traits, and germplasm, all of which may be patented.

Furthermore, some biotechnology patents are extremely broad in their scope or cover research tools that are very widely applicable that they can have the blocking effect on innovation. Thus, for example, Monsanto filed in 1999 patent applications in more than 80 countries on soybeans with enhanced yield derived by using a marker-assisted selection (MAS) technology. The patent covers "any cultivated soybeans containing certain genes or segments of DNA from "wild" or "exotic" soybeans identified through MAS".[xiii] The same firm owns a number of patents on other critical research tools used to genetically modified plants such as the recently granted US patent No. 6,174,724 that covers " all practical methods of making modified plant cells that employ antibiotic-resistance markers", a widely applied technique for transforming plants. According to G.Toenniessen of the Rockefeller Foundation, the Monsanto antibiotic-resistance marker patent "appears to be just another nail in the coffin of public-sector researchers' ability to produce transgenic plants with freedom to operate". [xiv]

Due to patent thickets and royalty stacking in biotechnology, pharmaceutical firms that develop end products find themselves involved in complex and costly multiple patent licensing negotiations and agree to the payment of royalties to all patent holders. These transaction and patenting costs often lead to higher prices, and consequently becoming out of the reach of most developing countries' patients. Furthermore, most biotechnology inventions are licensed exclusively, and this led in certain cases to serious restrictions on access to them as well as to monopoly pricing. Genetic tests are frequently cited to illustrate monopoly behaviour of some patent holders in this field. Thus, for breast cancer screening in France, for example, public health institutions are challenging the patent granted to Myriad Genetics on the BRCA1 gene. Although the challenge is on the technical merits of the patent, the dispute in fact is on the cost (at $2500, three times more expensive than domestically offered tests) and also because all DNA samples must be sent to myriad, thus eliminating the possibility of research by French clinical laboratories.[xv] The province of Ontario in Canada is also challenging Myriad's right to provide breast cancer genetic tests exclusively. Other national health authorities in Sweden, the UK and Italy have also voiced concern that patents on genetic tests can lead to abusive monopoly and that "unreasonable licensing practices pose a threat to public health by reducing access to screening procedures".[xvi]

Even if public research institutions in most developing countries are not yet directly concerned by the issues discussed above, indirect effects have already taken place in many ways. For example, a recent study on the impact of American patent policy on African Agriculture concluded that the US patent system and the existence of US patents adversely affect the ability of researchers to access and use different technologies for developing country purposes.[xvii] Legally, biological researchers in developing countries are not affected by patented research tools unless these tools are patented in these countries. However, this argument overlooks the indirect effects of patents granted in the developed world on use of patented technologies by researchers in the developing world. This is so for the following reasons:

Most research institutions and researchers depend heavily on aid from the developed world; and this aid is often tied to the protection of IPR by these institutions and countries. Consequently, institutions or countries that violate IPR may jeopardize their external funding, thus inhibiting useful application of biotechnology in these countries.

Developing country research institutions that are at present engaged in biotechnology rely often on collaboration" and "partnership" with Western biotechnology research institutions and firms for the necessary inputs including patents. These agreements frequently contain clauses pertaining to IPR protection.

To gain access to research tools or other enabling technologies and know-how, developing country researchers must enter into MTAs that impose restrictions on the use of technology, including prohibition of commercialization. MTAs thus operate as a de facto extension of the patent system to countries where the freedom to operate (FO) legally prevails. Many experts consider MTAs in biotechnology as an important barrier to the use of research tools in developing countries.

Patents can also affect biotechnology research in developing countries if it is applied to products that are intended to be exported to countries where such technologies are patented. This is so because the importation into counties where the technology is patented of products produced with a patented technology constitute an infringement, unless the use is licensed. As research institutions in developing countries often lack resources and skills needed to find their way through the patent thicket, the possibility that developed products may be exported to countries – where applied patents may be protected- is a deterrent to the development of biotechnology applications by research in these institutions and countries.

CONCLUSION

Extensive patenting of research tools, especially in biotechnology, has begun to have clear potential to inhibit access to technology in general and biotechnology in particular for developing country public health and food security purposes. In the future it may be much worse if the US model of IPR is imposed on the developing world through WIPO as well as through regional and bilateral agreements which are frequently used by developed countries to push through TRIPS-plus standards of IPR protection in developing countries. Consequently we recommend that developing countries should collectively work to:

- Establish a working requirement for biotechnology patents modeled on the working provision of the Paris convention. For example, if within if within 3 years, the patent holder has not exploited, others could apply to a designated authority for a nonexclusive license so that social utility be realized

- Establish a strong research and experiment exemption. This is needed to ensure that the conditions and cost of research remain manageable especially as research activities in most developing countries are already suffering from many constraints.
- Establish a compulsory license requirement so that public health and food security needs are satisfied.
- Exploit fully TRIPS' flexibilities and ambiguities.
- Avoid negotiating IPR in bilateral and multilateral trade and investment agreements.
- Incorporate article 27.3(b) of the TRIPS agreement that explicitly allows countries to exclude plants from patentability, provided they establish an effective *sui generic* system.
- Work and negotiate collectively and effectively so that their interests are preserved especially as a concerted effort by Western countries led by the United States is under way to achieve global harmonization of patent law far beyond that provided for by the TRIPS Agreement.

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