ROLE OF IPR IN BIOTECHNOLOGY TRANSFER - CORPORATE VIEWS

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The enhancement of intellectual property rights (IPR) under the TRIPs agreement[2] has to some degree been paralleled by an expansion of the literature on the optimal forms and roles of IPR systems. Economists have long concerned themselves (albeit with limited success) with such matters as optimal patent scope and duration. Public sector scientists have been particularly concerned with the effects of IPR on the dissemination of research findings, while a broad range of groups has expressed divergent opinions about the implications of IPR for the environment and traditional cultures, among other subjects. And industry representative groups like the U.S. Chamber of Commerce have in the past pressed hard for strengthened protection worldwide.

What is missing from this knowledge base is much of a concept of the perspective of how actual users of IP systems view its components and roles. We are aware, largely from surveys in developed countries, that the importance of IPR are seen quite differently in different sectors. Nogues (1990, pp. 11-14), for example, found executives on average ranked patent rights low as a component of R&D investment determinants. The reasons are generally conjectured as the ease of copying, the option to use alternative protection forms (secrecy, rapid technological progress, etc.), and differences in value and R&D costs. Grubb (1999, p. 377) gives some insights into the electronics sector where patents are used as 'bargaining chips' in patent-pooling and cross-licensing agreements. This he attributes to the common industry standard imposed by necessity and regulation. "In such a situation there is no room for individual monopolies to different technologies, nor for the use of patents to block the competition. [I]f they were used in this way, it would be impossible to develop and market any products at all." And research-based boutique companies use patents as a means of capitalizing research value at the pre-commercialization stage.

Yet even this limited information applies largely to developed countries. About views of the roles and importance of IPR in developing countries, essentially nothing is known beyond several surveys which sought practitioners' opinions of the adequacy of IPR in a range of developing countries. Mansfield (1995) for example surveyed a total of 180 executives and patent attorneys in the US, Japan and Germany. Focus was on the chemical and drugs, and machinery and electrical equipment industries which are believed to be particularly sensitive to intellectual property (IP) protection. Respondents were asked for 14 more technologically advanced developing countries to indicate when IP protection was 'too weak' to permit transfer of sensitive technologies to (a) invest in joint ventures, (b) wholly owned subsidiaries and (c) licensing key technologies. In general, protection levels were considered more adequate for machinery than chemicals and drugs. And while there was a high level of correlation among the national

[1] Prepared under WIPO Special Service Agreements.
[2] Annex 1C of the Marrakesh Agreement, 15 April 1994.

respondents, US firms were more likely to consider protection levels as too weak compared with responses from Japan and Germany, possibly due to national differences in the rate of innovation.

Sherwood (1997) also utilized a judgment-based ranking, relying on his own assessment of the conditions in 18 developing countries, most in Latin America. Each country was ranked on a 103 point scale for nine components including:

- enforceability (25 points)
- administration (10 points)
- copyright (12 points)
- patents (17 points)
- trademarks (9 points)
- trade secrets (15 points)
- life forms (6 points)
- treaties (6 points)
- general public commitment (3 points)

The scales were thoroughly researched with an interview period in each country. A verbal justification is given for deducting points in each component, but the overall allocation of points to each component is not discussed. And even if these scales were revealing overall, they provide little insight into the specific limitations of national IP systems, from the patent holder's perspective.

As a consequence of this large gap in knowledge about how private firms view patent rights in developing countries, a survey was commissioned by WIPO under a Special Service Agreement. The objective of this study is to collect information from major biotechnology firms on the effect of IPR in the recipient country on the willingness to transfer biotechnology to developing countries. Focus is on biotechnology firms which, in the forms of pharmaceuticals and agricultural applications, involves considerable R&D investment yet is relatively easy to copy. Thus, as IPR can be expected to be particularly relevant for these products, they serve as good indicators of the importance of IPR to technology transfer.

The intent of the survey was less a direct ranking of the adequacy of protection in countries and more an attempt to measure how firms involved in the transfer of critical technologies viewed the aspects of protection offered. That is, the focus was on the corporate patenting strategy, the understanding of the role of patents in transferring products and technologies to a range of developing countries. A secondary use was the development of an updated IPR ‘score’ which could be used in an empirical analysis of the importance of the strength on IPR on technology transfer.

SURVEY INSTRUMENT AND SAMPLE

In order to elicit the information sought, the respondents were led through a series of questions attempting to identify the firm’s very and somewhat sensitive products/technologies. The rationale for which countries and under what terms transfers

would be made was then elicited. The approach proved easy for the respondents to follow and provided useful information without the need to reveal anything confidential. A pre-screened version of the questionnaire was submitted to WIPO for some final corrections and clarifications. A copy of the survey form is attached as the Appendix.

The survey was sent to patent attorneys and licensing executives of agricultural and pharmaceutical firms in the US and Europe following an extensive period of instrument development and in-person interviews with six of the respondents. Public sector licensing officers were contacted as well. In total, 17 surveys and interviews were distributed with a response rate of 59 percent. The number of respondents in the biotech sector is limited for each responding firm completed the questionnaire jointly, one per firm. In practice, there are relatively few firms in the biotech area which have direct experience with a range of developing countries.

SURVEY RESULTS

It became clear that many firms have general perceptions of the operation of IP systems in their market countries which are not based on easily describable and observable components. They are responding rather to a generalized experience. One consequence of this situation is the difficulty inexperienced firms will have in deciding whether and where to transfer new products. Nonetheless, certain characteristics of the way firms view IPR systems across countries and their effect on the willingness to transfer technology became clear.

The survey results indicate, not surprisingly, that product market potential is the principal issue for private firms when identifying developing country markets. Public sector entities have different objectives including serving the public and product availability, but typically do not market products directly in developing countries or elsewhere. That is the task of licensees. Within the IPR sphere, the protectability of certain products and, particularly, enforcement of those rights (adequacy and speed of the court systems), were ranked second. Third in significance is the cost of protection, for which the Patent Cooperation Treaty (PCT) is seen as a source of efficiency and cost savings. The survey results for question 5 on the perceived limitations of IPR at the national level are tabulated in Table 1.

Table 1: Compost survey rankings of specific national-level limitations restricting the transfer of sensitive and valuable technologies

		Frequency Listed:		
	Reason	*1ST*	*2ND*	*3RD*
1.	exclusion from patent protection	.07	0	0
2.	inadequate scope of patent protection			
3.	patents inadequately examined	0	0	.14
4.	patent granting procedure too slow			
5.	inadequate term of protection			
6.	too liberal compulsory licenses or revocation			
7.	not member of Paris Convention			
8.	not a member of the Patent Cooperation Treaty	0	0	.14
9.	not a member of the Budapest Treaty			
10.	not member of the World Trade Organization			
11.	court system inadequate	.44	.36	.14
12.	law not evenly applied to all petitioners	0	.36	0
13.	court system too slow	0	.07	.57
14.	absence of effective trade secret protection			
15.	not member of the UPOV	.11	0	0
16.	inadequate Plant Breeders' Rights protection			
17.	existence of non-IPR barriers to market access (market too small)	.37	.14	0

Licensing executives showed a keen awareness of the role of IPR. That is, while the extent of IP protection is of great significance in selecting markets, firms are only too aware that products or technologies can be acquired in other ways than direct sales. Hence, for larger markets, a firm may take a chance on direct sales rather than loose initial sales to pirates in countries where IP protection is considered inadequate. Pharmaceutical companies seem particularly willing to sell products in countries where patent protection is judged inadequate, and even where patents are not sought. That is, effective available patent protection is desirable but not a necessary condition for pharmaceutical product sales. Agricultural firms for their part typically do not make the most current self-reproducible (i.e., non-F-1 hybrids) varieties available in the absence of PBR protection. This finding is supported by earlier studies which indicated access to current varieties was a major motivation for developing countries to adopt PBR and join UPOV (see Jaffe' and van Wijk, 1995; Lesser, 1999). Pharmaceutical companies at present are more sensitive to details of national laws, such as the availability and scope of protection, than are agricultural firms. That distinction will likely decline in the near future as countries comply with the minimum TRIPs requirements[3].

Perhaps of greater significance to technology access is the market size issue. All respondents indicated some markets are not served simply because the risk-adjusted

[3] As pharmaceutical products are not granted an explicit exclusion from patentable subject matter in Article 27, TRIPs compliance requires they be allowed patent protection if other protection requirements are met.

revenue potential is too small, meaning the costs of serving a market exceed the profit potential. Many of those costs are non-IP related, such as the access and cost factors encountered by many of the respondents in the Russian Federation. Yet the matter is partially IP-associated as effective IPR can limit market costs by reducing some risks and standardizing other practices. For that reason, Maskus and Penunbarti (1995) conclude small market countries require relatively stronger IP protection for the same level of access. That result, if substantiated, would provide a complex policy agenda for governments where markets for some products like seeds may be large while others, possibly pharmaceuticals, are small.

As a result of these practices taken together, the role of IP in technology transfer is more ambiguous than might otherwise be thought, and more significant for smaller than larger market countries. Perhaps most significantly though, the survey results emphasized how important a factor the enforceability of IP statutes is in a country. Jaffe' and van Wijk (1995) found *ex post* that PBR in Argentina indeed was not effective, and did not garner the expected investment in plant breeding, until rights were enforceable. The slowness of a national court system, poor standing of a foreign plaintiff, lack of technical competence, or inability to enforce a judgment once made were all reasons to downgrade the effectiveness of a national system. Duration of protection is a non-issue for few products have a market life approaching the term of patent, not to mention the standardization of the term under TRIPs.

DISCUSSION

A number of insights and issues arise from the questionnaires and associated interviews. The most pertinent of these can be summarized as follows:

Quality of Issued Patents: patent office administration incorporates a range of critical factors from efficiency and transparency to adequacy of funding and training of examiners. Of these, the competence of patent office staff is perhaps most significant. Such competency should be observable *directly* by examining the educational background and experience of staff members, and *indirectly* by the number of granted patents which are overturned by the courts. For the former, few patent offices provide information on the backgrounds of their employees. And as regards court challenges, as one survey respondent noted, cases brought reflect not a random sample of issued patents but rather those cases which are both ambiguous and potentially involving significant sums. And finally, patent challenges are more likely to be brought to trial by small firms for which a patent constitutes a (the) major asset (Grubb, 1999, p. 373). As a result, differences across countries can reflect a number of factors in addition to the actions of a patent office. The measure is not uni-dimensional. Then there is the issue of the transparency of a national court system which can affect the outcome, and the absence of a database on cases brought and their resolutions. Ginarte and Park (1997, p. 290) identified related reasons for abandoning an attempt to use a measure of complaints against a patent system as a measure of patent office competence.

What is and remains lacking then is a means of measuring the competence of national patent offices. This would provide useful information for firms considering transferring

products/technologies to countries with which they are unfamiliar as well as a basis for national policymakers to understand how best to enhance IPR office standards.

Enforcement: enforcement takes particular relevance due to the emphasis placed on it by the survey respondents. This is a significant future issue for the TRIPs stipulations regarding the operation of IP court systems are rather general. Article 41 requires fair, timely and equitable procedures while Articles 44 and 45 refer to the availability of injunctions and damages. From Table 1 it is abundantly clear the overriding issue with firms is general inadequacy of court systems, followed by perceived prejudice and delays. The specifics of what courts are permitted to act on seems less relevant.

Whether the Article 41 requirements are sufficient to reform national court systems to the degree required by biotechnology suppliers remains to be seen. Gervais (1998, p. 197) sees the section as "one of the major achievements of the negotiation." He though places emphasis on the Article 41.5 allowances to "prevent infringements, not just to stop them once they had started." While significant, that issue was of less importance to the respondents than that of general court operations. General court management does present a major challenge, certainly to the countries, as well as highlighting the fact that there is no international body responsible for assisting in legal reform. Indeed, according to knowledgeable individuals, no systematic process is in place to assess national court systems nor is it clear just what standards would be used.

Market Size: small markets are the second most cited reason firms do not transfer technologies to selected countries. Presumably, the transaction costs and risks of entering a market outweigh the profit potential. In more traditional sectors, independent distributors could be utilized, but the complexity and significance of biotech products presumably prevents that option. Assisting these smaller markets in accessing high technology goods will be a major challenge.

One approach related to IPRs is to reduce the transaction costs through further standardization. Certainly the PCT serves an important part of that role. The utilization of regional patent offices would provide an additional contribution, regional patents a further one. Whether small market countries need *stronger* IPR protection or only protection provided *more efficiently* requires more research.

CONCLUSIONS

This survey provides some insights into how biotechnology firms view the operation of IPR systems in developing countries, particularly as regards the transfer of sensitive and valuable technologies. As for any survey, caution should be applied when generalizing these results for they apply strictly only to biotechnology-related firms with its own particular characteristics. That said, the results do appear to be generally applicable. Second, when generalizing the results, is the matter of separating the general issues from sector and firm specific ones. That is, individual firms clearly have differing general policies, some which accept more risk of losing control over a product in seeking additional markets and others which are more risk averse. Such general attitudes do affect the survey results, but understanding their basis requires a more detailed firm level

analysis than is the objective of this study. And finally, in the biotechnology sector at least, no one firm sells products in a wide range of countries, so the knowledge base of each respondent is limited. In statistical terms, this means there are few replications for many countries and one participant's perceptions can be given significant weight. However, in the case of this survey, the results are very consistent so the above concern, while present, does not seem to apply.

The most significant finding here is that enforcement concerns are paramount in limiting the willingness of firms to transfer sensitive and valuable technologies to specific countries. In this post-TRIPs era, the concern is less with legislation-based rights and more with the timely and transparent operation of national courts. Whether the TRIPs Article 41 mandates are sufficient to overcome this perceived problem is not clear, but the operation of a court system is a consequence of many aspects of national government structure so will not be readily changed. In any event, assistance will likely be needed, yet there is no international body charged with providing that support.

Second in importance is the quality of decisions made by patent offices. This, too, presents a major organizational and training challenge to countries, but WIPO has ongoing and successful efforts to assist national patent offices in this regard. Meeting TRIPs challenges, the survey results suggest, will necessitate sustaining and expanding those efforts.

The latter point is associated with a third national-level limitation identified in the survey, small national markets. IPR is associated only to the degree that national differences impose country-specific costs. One approach to overcoming those is the use of centralized patent office activities, such as regional offices, re-registration of patents granted elsewhere, or designation of PCT International Searching Authorities for searches in some sectors. The best specific approach or approaches need to be identified.

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Appendix: Survey Instrument

ROLE OF INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY TRANSFER

QUESTIONNAIRE OUTLINE

An attempt is being made in conjunction with the World Intellectual Property Organization (WIPO) to understand the effects of intellectual property rights (IPR), particularly patents and plant breeders rights, on the willingness of enterprises and other technology owners to transfer living, self reproducible products and technologies in their creation to developing and certain other countries. While these products require heavy investment to develop, they are fairly easily copied and there is considerable risk of infringement. Often, therefore, an effective national intellectual property system is relied upon to provide a conducive environment for the transfer of such technology. As IPR systems are being upgraded worldwide in line with privatization of many government activities in general, and the WTO/TRIPs requirements in particular, it is important to understand how the specifics of national systems affect the transfer of plant and animal-based technologies and products. Your assistance in answering this questionnaire from the perspective of your enterprise will be of great assistance in that understanding. Further, better understanding of the dynamics of the transfer of such technology to developing countries will enable governments of such countries to fine tune their systems to be more receptive to such transfer and make more effective use of such technology.

All answers are **confidential** and will not be revealed in a way which could be attributed to an individual enterprise.

/...

The format of the questionnaire is to cast the questions in terms of products classified by you as A, B or C in descending order of importance to the enterprise.

1. *Classification of Products*

A. Do you (or can you) rank the products of your enterprise in the order of most valuable (or current) to least valuable? For example, you may have a progression of hybrid varieties from current to outdated.

_____ YES, it is reasonable to rank our products in terms of market value.
Please continue.

_____ NO, such a ranking makes no sense for us.
Thank you, please return questionnaire.

B. If you can order your products, is it feasible to think of a three tier system, A, B and C, with A most valuable?

_____ YES, I can rank products as A, B or C.
Please proceed.

_____ NO, such a ranking makes no sense for our enterprise.
Thank you, please return questionnaire.

Comments

2. *Examples of Products*

Can you give examples of products which might be classified as A, B or C? As examples, an ‘A’ product might be this year’s hybrid or a GMO with ‘stacked’ traits, while a C is a five-year-old hybrid or a GMO that produces only a moderate dose of the Bt toxin.

PLEASE NOTE: the intent is not to ask for confidential information, but rather to make answers to the subsequent questions more concrete. Thus, an example can be left fairly general.

1. Example of an ‘A’ product:

2. Example of a ‘B’ product:

3. Example of a ‘C’ product:

Comments

3. *Reasons for Classification*

What are the principal attributes of the products identified above which caused them to be identified as an A, B or C?

Please **CIRCLE THE TWO MOST IMPORTANT**.

a. Sales revenue potential.

b. Ease of copying.

c. Narrow vs. broad applicability (e.g. variety compared to technology).

d. Corporate policy for product types.

e. Importance of product category to corporate income (i.e., barley may be a minor product category compared to maize).

f. Rate of product obsolescence.

g. R&D investment in products.

h. *De facto* established market share and reputation of product in meeting the needs of a particular market.

i. Other

Please explain:

Comments:_____

4. *Transfer of Products*

A. Do you consider the level and effectiveness of legal protection when making decisions on marketing particular products in specific countries or in entering into licensing arrangements, partnerships, joint ventures etc., in such countries? That is, are there some countries in which you would be prepared to sell type C products or enter into other such collaborative arrangements as described above vis-à-vis type C products but not type A because of ineffective legal protection?

____ YES, effectiveness of legal protection is considered when making decisions as to whether we should enter a particular country.
Please continue.

____ NO, legal protection is not considered when making such decisions. Please indicate why.
Thank you. Please return questionnaire.

Comments

B. For the countries listed below, please indicate your highest ranked products which you would be willing to market there using the product descriptions from question 2 above. Further cross out those countries for which you do not have a marketable product.

Please check highest ranked product which applies

COUNTRY	MKT. PRODUCT A?	MKT. PRODUCT B?	MKT. PRODUCT C?
Algeria			
Argentina			
Brazil			
Chile			
China			
Côte d'Ivoire			
Egypt			
India			
Indonesia			
Iran			
Kenya			
Malaysia			
Mexico			
Nigeria			
Philippines			
Poland			
Republic of (South) Korea			
South Africa			
Syria			
Russian Federation			
Thailand			
Uzbekistan			
Venezuela			

Please add to this list other countries which are not indicated and which are of interest to you

Comments

5. For the countries listed below, please draw a line through those to whom you would be willing to sell type A products. For the remainder, please identify what, in particular, is lacking in the country which causes you not to sell type A products as identified in question 2.

KEY:

a. exclusion of key products/processes from patent protection
b. inadequate scope of patent protection
c. patents are inadequately examined to be meaningful
d. patent granting procedure too slow
e. inadequate term of protection
f. loss of protection: too liberal compulsory licenses or revocation standards
g. not member of Paris Convention for the Protection of Industrial Property
h. not a member of the Patent Cooperation Treaty
i. not a member of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure
j. not member of the World Trade Organization
k. court system inadequate to enforce intellectual property rights
l. law not evenly applied to all petitioners
m. court system too slow to provide meaningful protection
n. absence of effective trade secret protection
o. not member of the International Convention for the Protection of New Varieties of Plants (UPOV)
p. inadequate Plant Breeders' Rights protection
q. existence of barriers to market access other than IPR.

COUNTRIES	1st LIMITATION	2nd LIMITATION	3rd LIMITATION
Algeria			
Argentina			
Brazil			
Chile			
China			
Côte d'Ivoire			
Egypt			
India			
Indonesia			
Iran			
Kenya			
Malaysia			
Mexico			
Nigeria			
Philippines			
Poland			
Republic of (South) Korea			
Russian Federation			

South Africa
Syria
Thailand
Uzbekistan
Venezuela

Comments

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