

# CURRENT SCIENCE

Volume 88 Number 10

25 May 2005

EDITORIAL

## Patents, Laws and Science

Until a few years ago researchers in academic institutions and national laboratories rarely worried about 'intellectual property (IP) rights' and patents. The pharmaceutical industry, in India, thrived on a patent regime that protected processes, but not products. The drug discovery process is a long tortuous and expensive undertaking, which results in new, clinically useful molecules. Once a valuable molecular structure is uncovered, its production and marketing was legal, under the 1970 Patent Law, as long as an alternate process was developed. Indian industry built its skills in process chemistry and upscaling production, resulting not only in a phenomenal growth in the area of pharmaceuticals, but more importantly in making drugs available at affordable costs. The discovery process requires a great deal of complex, inter-disciplinary basic research; whereas, local strengths in medicinal and organic chemistry and in process development could be readily exploited in a 'process patent' regime, which underplayed the discovery effort. Globalization and the rise of the World Trade Organization (WTO) has changed this scenario. For the last few years the shadow of the Agreement on Trade Related Aspects of Intellectual Property Rights (better known by its curiously apt acronym, TRIPS) has loomed on the horizon. With the WTO serving as an enforcer, India has been nudged firmly towards a new set of patent laws, which now bring into place a product and process patent regime.

When Parliament finally voted in the Patents (Amendment) Bill 2005, towards the end of March, few commentators were unguarded in their praise. Most analysts seemed critical of a new law which seemed to have conceded far more than demanded by international agreements. In a well-argued critique, the important point was highlighted that 'the Patents Bill made 74 amendments to the Patent Act of 1970, thus taking it much beyond the requirement of TRIPS. As the bill now stands, ... it fails to protect the public from the aggressive monopolies that patents confer on the right holders' (Gopakumar, K. M. and Amin, T., *Economic and Political Weekly*, 9 April 2005). I rather liked the use of the term 'aggressive monopoly', which conjures up an image (that often is all too real) of an excessively powerful multi-national, protecting the beneficial products of science beyond all reasonable limits. In the

pharmaceutical industry every known trick is employed to extend the patent life of products; science sometimes comes to the aid of the legal departments, most notably in the growing importance of polymorphs. To the uninitiated, a polymorph is merely another physical form of a substance in the crystalline state; its molecular structure and chemistry remain untouched. Polymorphs are patentable, resulting in a new industry, which magically produces polymorphs to extend a legal hold on products (although the same device can sometimes be used by a powerful competitor to muscle in on a large market for a promising drug). In an assessment of the new law a commentary in the *Economic and Political Weekly* concluded that the 'result is a more complicated and confused law', which seemed to be a consequence of not having 'any overall policy objective to achieve, other than pleasing all sides' (16 April 2005). While the US patent system is a model that countries, the world over, seem compelled to follow, the commentary noted that 'there is increasing skepticism around the world over the patent system as it has evolved so far, more particularly in the US'. This critique reaches a damaging conclusion that 'India has swung from one extreme to the other, moving from the 1970 law that was clearly anti-patent to a law that is pro-patent applicant but not necessarily pro-innovation'. It is clear that we now have a 'TRIPS-compliant' law; its effects on drug prices, especially the products of the most recent research, remain to be reliably assessed. There is an almost universally shared perception that the prices of many life-saving drugs will rise, maybe even to levels that make them largely unaffordable in the poorer countries of the world. This is a problem that will eventually have to be addressed by governments and international agencies. Undoubtedly, public subsidy and international aid will be the available weapons of redress; unfortunately, contributing excessively to private profit from the public exchequer is not going to be a strategy that will make everyone comfortable. An editorial in *The Hindu* emphasized that 'the Government must not treat TRIPS as a closed chapter. There is a process of review and India must effectively and persuasively advocate a much greater relaxation of key Articles relating to public health' (24 March 2005).

The culture of patenting scientific research results (I deliberately do not use the word 'innovation' here) is well developed in the United States. Protecting areas of activity with a complex array of patents is a practice that has been made acceptable by multinational corporations. Even research tools and techniques, that would have once passed seamlessly into the public domain, are now protected by a patent firewall. Academic institutions sense that there is money to be made from their research output and rightly feel that a fair share must accrue to the institutions, which provided the ambience and facilities for the research. American universities are doing well as demonstrated by a recent survey. The Universities of California (and there are several institutions lumped together here) top the list with 438 patents in 2003, while Caltech and MIT follow with 139 and 127 patents, respectively. The top 10 contains some well known names, Stanford, Columbia and Cornell. Surprisingly, Harvard, Yale and Princeton were missing; a sign, perhaps, that the Ivy League is a little less affected by the inroads of industry-driven research. The statistics on national rankings make interesting reading. A list of international patent filings under the Patent Cooperation Treaty (PCT) in 2003, shows the United States at the top with 39,250 patents followed by Japan (16,774), Germany (13,979), United Kingdom (6090), France (4273), The Netherlands (4180) and the Republic of Korea (2947). Sweden, Switzerland and Canada make the top ten, while China, India and Brazil are missing (Harding, A., *The Scientist*, 27 September 2004, p. 52). A summary of the fees levied by the US Patent and Trademark Organization (USPTO) suggests that the fees for filing and minimal maintenance would be about \$3500, which may act as a deterrent to indiscriminate filing from poorer countries. The patent world and the governmental and legal systems that enforce the rules of the game are clearly dominated by the developed world.

In India, the Council of Scientific and Industrial Research (CSIR) has been the prime mover in pushing for a vigorous program of generating and protecting 'intellectual property', a term that leaves me with an uncomfortable feeling; 'exploitable research results' may be a more appropriate descriptor. The CSIR has successfully propagated the philosophy of protecting potentially useful research and holds the largest patent portfolio amongst Indian organizations. An article in this issue (Shukla, D. B., p. 1553) provides interesting statistics, which suggest that our academic institutions (IITs and IISc prominent among them) are slowly realizing the importance of being alert to the possibility of practically exploiting interesting research results. The absence of a professionally run 'IP cell', in most institutions, can be inhibitory to spreading the 'culture of intellectual property protection in research and development'. Filing patents can also be an expensive and slow process, involving documentation that can drive many creative scientists to distraction. Most institutions do not readily have access to patent attorneys, who

can smoothen the process of IP protection. Eventually, a substantial patent portfolio can be expensive to maintain, especially if patent licensing does not lead to significant income. Even as scientists get used to the idea that patents may count as much as publications in assessments of research output, there is a danger that frivolous patenting may become a reality that our institutions may have to confront.

Universities and public institutions can benefit from a spread of the culture of patenting research outcomes, if they become partners with industry. A share of the profits from a discovery that has led to a marketable product is something that most academic administrators would welcome. In the United States, legislation has ensured that 'government renounced intellectual property claims on research supported by federal funds in universities or other non-government institutions' (Kennedy, D., *Science*, 2005, **307**, 1375). In an editorial marking the 25th anniversary of the Bayh-Dole Act, the editor of *Science*, Donald Kennedy notes that 'this legislation has had a profound impact on science in the United States and, indirectly, in other nations as well'. While the Bayh-Dole Act opened the way for universities to profit from publicly funded research and speeded up the process of innovation, there is some concern, a quarter of a century later, that 'corporatization of universities' may entail an unaffordable academic cost. A recent book *University Inc: The Corporate Corruption of Higher Education* (Washburn, J., Basic Books, 2005) addresses the issues raised by university-industry links. I have not obtained a copy of the book, but a review suggests that the book must be required reading for analysts and policy makers. The concluding sentence is provocative: 'For the world outside the United States – particularly southeast Asia, where research is more related to health and wealth creation – there are lessons to be learned... The financial imperatives need to be kept in check to avoid serious damage, not just to science but to people's lives' (Richards, G., *Nature*, 2005, **434**, 824).

In India many problems related to patenting activity in public institutions remain unaddressed. There is no legislation that governs the role of governmental funding agencies in the ownership of 'intellectual property', generated in research sponsored at academic institutions. The multiplicity of funding agencies, which do not coordinate their activities, can lead to a great deal of confusion. The situation in projects which involve multiple partners, government agencies, academic institutions and industry can be bewildering. There is a clear need to learn some lessons from the Bayh-Dole Act. Government must act as a facilitator of technology transfer from universities, while ensuring that public funds are invested in areas that may lead to notable progress in science or in fields that have the greatest possibility of benefiting the country.

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