

Intellectual Property Protection – Lifeline for the Pharmaceutical Industry

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Abstract: Pharmaceutical patents are often an area of controversy. Yet, knowledge, *i.e.* intellectual property, is the capital without which many modern biotech companies could not raise money to finance their research. Patents are the lifeline of the pharmaceutical industry: it is relatively easy to copy a pharmaceutical product, and no other industry spends as much on research and development. Protection of intellectual property has stimulated competition on innovation and contributed to medical progress for the benefit of patients.

Keywords: Biotechnology · Health care costs · Intellectual property · Patents · Pharmaceutical industry · R&D

In the 15th century, Venice, a centre of art and culture, was a major power in Europe. Since it possessed no real economic hinterland of its own, the city was forced to rely on military campaigns and the skills of its inhabitants to survive. The Venetians were not only active in glass blowing, but also in dyeing, weaving, sugar refining, silk making, and printing. The Venice of the 15th century carried out what would today be described as innovation-directed industry, in which business survival was dependent on new developments. The Venetian authorities recognised the special value and the economic contributions of inventions. In 1474, they passed a law which gave the inventors of new machines, tools and instruments a certain degree of protection against imitation for a period of 10 years. The idea of the patent was born [1].

Today, patents and the pharmaceutical industry form a symbiosis which is inseparable. Industrial property protection, and, in particular, patents, form the lifeline for the research-based pharmaceutical industry. Investment of, at present, more than \$500 million for the research

and development of one new medicine which reaches the market can only be justified because intellectual property protection grants a limited term of exclusivity for the commercial exploitation of such an invention. Yet, patents were and will probably continue to remain a contentious issue. There is an inherent tension between the limited monopoly of the patent which gives the successful innovator a fair chance to recoup its investments and many governments' interest in containing health care costs.

Today, patentability of biotechnological inventions is controversial. However, the idea that inventions in biotechnology are as worthy of protection as other inventions is not simply the suggestion of proponents of modern gene technology – it was already the opinion of Louis Pasteur, the great French scientist. In 1873, Pasteur was granted the American patent 141072 for the production of a bacteria-free yeast, which improved the fermentation process in the brewery industry. There is a direct line from Pasteur's invention to today's innovations in biotechnology.

Strong worldwide patent protection is essential to spur pharmaceutical innovation. A survey based on a random sample of 100 US firms in different industries confirms that patent protection is essential for companies investing in pharmaceutical R&D [2]. Drug companies indicated that 65% of their medicines would not have been developed or commercially introduced if patent protection were

not available – a much higher figure than reported by any other industry.

The huge cost of research and development of one new medicine and the relative ease of copying provide an explanation for the importance of patent protection for major pharmaceutical companies. For drugs introduced in 1990, it is estimated that R&D costs are approximately \$500 million [3] whereas the cost of demonstrating the bioequivalence of a generic product is approximately \$1 million [2].

Yet, the relevance of strong intellectual property protection goes far beyond major multinational corporations. Guaranteeing the protection of intellectual property in research using the modern tools of molecular biology is essential for many start-up biotech companies to survive. A European survey done in early 1997 [1] showed that all nine patents on animal models granted by the European Patent Office in Munich were owned by either universities or 'start-up companies'. Many of these firms do not yet have products for sale, and for them it is essential to protect their intellectual property as the only real capital they have. These firms are part of the 'New Economy' and their staggering market capitalisation is generally based on analysts' assessment of their IP valuations. The importance of this could be seen in mid March when the stock of many US biotechnology companies plunged following a joint statement by UK Prime Minister Tony Blair and US President Bill

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Clinton calling for all raw data obtained on human genes to be 'made freely available to scientists everywhere'. The statement as such provided nothing new. In contrast, it emphasised the importance of patent protection as vital for stimulating research in the biomedical area. Yet, the mere perception of a weakened commitment to the protection of intellectual property wiped out billions of dollars from the market capitalisation of biotech companies.

To put the case for the pharmaceutical industry's interest in patent protection simply, two factors have to be borne in mind: first, it is relatively easy to copy a pharmaceutical product, and, second, no other industry spends as much on research and development as the pharmaceutical industry. Over the past 20 years, the percentage of domestic US sales allocated to R&D has increased from 11 to 20.8% [4]. Swiss pharmaceutical research companies also spend approximately 20% of their global sales on R&D. In contrast, the computer industry spends just above 8%, the electronics industry less than 6%, and the huge run-up costs to the building of a new airplane amounts to less than 4% of sales. On average it takes ten to twelve years from patent filing to market launch of a new medicine, out of 10 000 substances tested only one reaches the market, and only three out of every ten new medicines will ever recover the huge R&D costs.

In the context of the controversy surrounding the international trade debate, there are a lot of myths surrounding the issue of patents. A first such myth is that patents create monopolies. In reality, patent protection offers protection only for a limited time. The exclusivity is limited to eight to ten years, in countries with patent term restoration, to 14 to 15 years, and, in reality, most new introductions compete with similar products. Competition is fierce in almost all therapeutic areas, and even new chemical entities which introduce a novel therapeutic concept are followed by competitor products within a short time period. Over the last two decades, the time lag in which a company enjoys real exclusivity has shortened considerably: from several years in the case of the first beta-blocker to just a few weeks in the case of the first protease inhibitor which has proved very effective in reducing mortality and morbidity of AIDS.

A second myth is that patents are a significant factor in escalating health care costs. This argument ignores the fact that there is a clear and established link be-

tween patent protection and the rate of innovation, but no such link between the strength of intellectual property protection and price levels. France and the United States are two countries with traditionally strong patent protection, yet the price of medicines in these two countries is quite different. The same goes for access to medicines, a theme which is increasingly clouded by demagoguery rather than thorough analysis. India is a country with a thriving generic industry. Yet many people who are HIV-positive do not have access to copies of AIDS medicines. Fact is that rhetoric is often used to protect the interests of vested local industries. According to a study done by CAEME, the organisation of multinational companies in Argentina, unit prices of national products in Argentina exceeded those of multinational companies by an average of 14% to 48% in the years between 1982 and 1993.

Another myth is that only multinational companies are able to engage in research and development of pharmaceuticals. The fact is that there is no true innovation without proper intellectual property protection. Canada, after strengthening intellectual property protection, experienced dramatic growth in R&D investment. In 1979, 2.7% of pharmaceutical sales was invested in R&D. That figure had increased to 15.7% by 1997 [5]. Between 1987 and 1997, pharmaceutical research spending in Canada rose by more than 700%, and new R&D investment exceeded \$4.6 billion.

A typical example of the relationship between strong patent protection and pharmaceutical innovation is the US Orphan Drug Act of 1983 which provided limited market exclusivity and tax credits for drugs used for small patient populations. In the decade following the enactment of the Act, 99 drugs for rare diseases were marketed, up from ten in the decade before the enactment. In 1999 alone, more than 20 drugs for rare diseases were approved by the Food and Drug Administration.

Major beneficiaries of the incentives for successful innovators are small biotechnology firms which mostly lack the financial resources to turn new knowledge into marketable products. The cost of developing new medicines far exceeds the capacities of most such firms, and so knowledge and know-how become their real products. Knowledge, however, can only be profitable if it is appropriately protected so it cannot easily be copied. Patent law offers this protection and thus influences the dynamics of economic de-

velopment. In addition to conferring economic advantage, patent protection has other functions:

- It recognises the inventor's ownership of the intellectual property
- It recompenses the inventor for something that can be widely used throughout society
- It encourages innovation
- It encourages that technical discoveries are published and propagated at an early stage.

Without patents, the collaborative alliances between major pharmaceutical companies and start-up biotech companies which, to a significant extent, have funded the research efforts of modern biotechnology would not have been possible. Patents alone ensure that the knowledge obtained from small- and medium-sized firms remain with the partners and that the relationship is one of business partners and not of exploitation.

Given the success story of strong intellectual property protection, one may wonder why there is so much political debate about the IP issue. A lack of the understanding for IP case is still widespread. A survey among Swiss academics done by the Science Committee of the Swiss Parliament showed that patents are of little concern to most members of the science faculties of Swiss universities. The problem is not confined to Switzerland as can be seen from a 1996 quote of the then Chairman of the German Doctor's Federation that he regarded the notion of human gene patenting as absurd.

Industry needs to respond to such challenges. First, it needs to clearly explain the strict criteria for patentability, *e.g.* the human body or parts thereof *per se* are not patentable. An invention

- must be new
- must be invented, and not just discovered
- must be susceptible to commercial use.

This also means that an invention must be repeatable, and cannot simply be due to chance, *i.e.* a DNA molecule which does occur in nature can be patented after it has been isolated and can be reproduced subject to meeting the above criteria. These criteria are strict and, if properly applied, clearly limit excessive claims based on computerised mapping of genes or gene sequences.

In the course of the occasionally heated debate about biotech patentability some of the basic truths tend to be forgotten: first, that patents encourage disclosure of information as against secrecy, second, that patents encourage invest-

ment in research and development for the benefit of mankind, and third that they give no right to use inventions where other regulations such as, *e.g.* animal protection laws, are involved. And above all, patents are a main driver for future pharmaceutical innovation which will help alleviation, early detection and prevention, and cure of disease.

Received: March 21, 2000

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Chimia 54 (2000) 320–324
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ISSN 0009–4293

Enforcement of Intellectual Property Laws

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Abstract: The present article concentrates on Patent Law with some comparison with the less contested problems of Trademark and Copyright enforcement.

By the Grant of Patents, the State conveys to the Patent Owner an absolute right over commercially applicable technical achievements for a limited period of time. The Patent Owner has an exclusive right to exercise the invention, to permit third parties to work the invention against compensation and to prevent its unauthorised use. Effective patent protection requires not only a reliable system of grant and administration but equally important an effective system of enforcement. The TRIPs agreement which forms part of the GATT Agreements concluded in Marrakech in 1994 has established uniform minimum standards of enforcement practically worldwide. The implementation of the TRIPs Agreement is far from completed.

In Switzerland 26 Cantonal Courts are competent for patent enforcement. With the exception of the five Courts of Commerce (Zürich, Bern, Aargau, St Gallen and Geneva) the competent Courts have no technical knowledge and little experience in patent matters. The Courts are forced to rely almost exclusively on outside experts even in injunction proceedings. As a result, patent enforcement in Switzerland is often very slow and there is little reliability and continuity of jurisprudence. As the Supreme Court may only re-examine questions of law and considers itself as bound by the facts established by the Cantonal Courts including Court Expert opinions it is unable to impose the desirable harmonisation of patent law jurisprudence. Patents that cannot be properly and timely enforced are of limited value. Insufficiencies of the enforcement procedures in Patent Law in Switzerland are detrimental to the encouragement of research and development and thus to the Swiss economy. It would be desirable to concentrate the enforcement of Patent Law in Switzerland to a Federal Patent Court with panels of technically trained judges composed by a Court of First Instance (possibly with two Chambers for the German and French part of the Country) and a Federal Court of Appeals following the US example.

Keywords: Enforcement · Intellectual property · Litigation · Patents · TRIPs

1. Introduction

'Intellectual Property Rights' (IP Rights) are legal rights which protect mostly intellectual, creative achievements as opposed to property rights in material objects. Three different groups of protection may be distinguished:

a) *Protection by Formal Act*

Achievements which fall in this category are:

- i) Inventions protected by Patents
- ii) Distinctive Signs consisting of words or figurative elements protected as Trademarks

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