ent may not be that easy to achieve. A system where harmonization would concentrate on the most important aspects of patent law, and leave other, less relevant, aspects to the discretion of national laws may already constitute a big step forward. In the meantime, the worldwide discussion on further harmonization of patent law must continue.

Some possible steps in order to achieve further improvements on harmonization may be the following:

- easier access to and concentration of existing databases on prior art;
- harmonization of the main conditions of patentability, for instance novelty (including the definition of prior art), inventive step, industrial applicability (utility), disclosure requirements, *etc.*;
- mutual recognition of search and examination results by national and regional patent offices, based on agreed guidelines and training of examiners.

Some of the above measures are already under consideration within, *e.g.* the framework of the Trilateral Cooperation (Japanese Patent Office, European Patent Office, United States Patent and Trademark Office), or under the PCT, as mentioned earlier. Whether these efforts will ultimately lead to a harmonization of the substantive criteria of patent law, or even to a unitary international patent system, which would constitute a major step towards the reduction of costs, remains an open question. The answer depends on the willingness and the solidarity of all players involved. It seems, however, that all the users, including applicants, practitioners and patent Offices can only benefit from future progress on harmonization of patent law.

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[1] The PLT documents, as well as other documents for the Diplomatic Conference for the Adoption of the PLT, may be found on the website of WIPO: *http://www.wipo.int/*.

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Importance of Trademark Protection for the Chemical and Pharmaceutical Industry

Werner Haring*

Abstract: This article gives an overview of the marked shift which trademark protection has undergone during the past years. Burning trademark issues in the chemical and pharmaceutical area are parallel imports, central pharmaceutical product registration in the EU, counterfeiting, and Internet domain names.

Keywords: Central product registration · Community trademark · Counterfeiting · Internet domain names · Madrid Agreement Protocol · Parallel imports · Pharmaceutical industry · Trademarks

For many years, intellectual property law – and trademark law in particular – led a shadowy existence. In management circles at many companies the brand was reduced to 'trademark, product labeling and protection law'. It thus came to be regarded as an instrument whereby short-term goals could be achieved. This attitude prevented trademarks from coming into their own, since an emphasis on labeling and rights of use often prevents a trademark's energy – its essential value – from being released.

Since the early 1990s, however, trademark thinking has undergone a marked shift.

During the last decade trademarks have increasingly been used as an important strategic instrument, even in companies not involved in consumer business.

With the realization that trademarks are essentially a positive force in the consciousness of the consumer of goods and services, they are being increasingly integrated into management responsibility. This

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With the realization that trademarks are essentially a positive force in the consciousness of the consumer of goods and services, they are being increasingly integrated into management responsibility. This new approach has led to a global boom in trademark law. It is now legitimate to speak of a trademark 'megatrend', characterized by:

- intensive international harmonization efforts, *e.g.* EU trademark harmonization and numerous alignments of national laws,
- introduction of the EU trademark on April 1, 1996 [1], expectations being exceeded many times over with more than 100 000 new applications,
- launch of the Madrid Agreement Protocol, also on April 1, 1996 [2]; with many countries already being signatories, this agreement promises to be of major international significance in the future.

1. Significance of Trademarks in the Pharmaceutical Market

In the past, trademarks already played an important role in the highly sensitive pharmaceutical market. Now the rapid pace of modern developments is accentuating the significance of the drug trademark factor.

In **technical** terms, the trademark of a respected company stands for quality. The drug trademark conveys to the authorities, doctors, pharmacists and patients a guarantee of safety and therapeutic efficacy for the whole product, and not just for the active substance, as is the case with generics.

In **commercial** terms, it is useful for all parties – above all, patients – to sell a drug under a tradename, rather than using complicated chemical or generic denominations.

With an easily memorized trademark and the associated guarantee of quality, the pharmaceutical manufacturer is invoking the reputation of the company as a whole. Of course, defects must be avoided at all costs, to prevent fatal damage to the company's reputation.

In **economic** terms, the trademark carries a high value-adding potential in the pharmaceutical market. This in turn acts as an incentive for the manufacturer to invest in new research programs, or to provide comprehensive medical information on new drugs. In a somewhat emotional fashion, part of the blame for the explosion of healthcare cost has been laid on branded pharmaceuticals.

In this debate, certain points of difference from generics are overlooked, namely that branded drugs

- state where the product originates,
- establish the manufacturer's responsibility,
- provide a guarantee of quality, in particular consistent bioavailability and therapeutic efficacy, and
- justify the confidence of doctors, pharmacists and patients.

Trademarks are used in the OTC sector (= Over The Counter), as well as in the ethical sector, but with a markedly different customer orientation. Advertising is addressed not to the scientifically trained physician or pharmacist, but directly to the patient as a consumer of non-prescription drugs.

Brand management and strategic positioning are clearly oriented towards the consumer goods sector and for this reason require a high degree of responsibility on the part of companies active in the OTC sector. The top priorities are clearly worded information for patients, rigorous screening in terms of trademark and competition laws and the need to prevent consumers from being misled.

With generics on the one hand and OTC products on the other, branded pharmaceuticals face fierce competition. Still more pressure, however, stems from so-called parallel imports, especially in Europe.

2. Parallel Imports and Intellectual Property Law

With parallel and re-imports, what is at stake is the extent to which considerations of national sovereignty permit a pharmaceutical manufacturer to prevent third parties from importing trademarked drugs which have been manufactured by a foreign licensee or produced by the manufacturer himself and subsequently exported.

Imports of this kind are attractive to third parties since drugs originating from the same manufacturer are often cheaper abroad. According to economic theory, parallel imports may indeed help to reduce price distortions provided that free market conditions prevail and the parallel importer offers an identical product.

In some EU countries, however, drug prices are kept at an artificially low level by state controls; parallel imports are thus a consequence of previously created market distortions. The bulk of the profit arising from this type of business accrues to the wholesaler or retailer concerned. In what are surely illegitimate efforts to maximize profits, trademark law is grossly breached and even product safety is jeopardized (*e.g.* repackaging from glass to plastic bottles and cutting up blister packs). Numerous lawsuits have been brought to the European Court of Justice by research-based pharmaceutical companies. To date, however, these have not put a stop to the erosion of trademark law in the European pharmaceutical market.

3. Trademarks and Centralized Registration in the EU

While the industry has in general welcomed the introduction of an economic, centralized product registration procedure for the European pharmaceutical market, one mandatory precondition has encountered major resistance – the requirement that the product submitted for registration should have an identical trademark registered in all EU countries [3].

Notwithstanding all the efforts to achieve internationally or even globally uniform trademarks, trademark practitioners agree that in the pharmaceutical sector, with its profusion of registrations, it is extraordinarily difficult to implement a uniform trademark for all EU member states.

In what seems to be an overzealous attempt to achieve a functional internal EU market, obstacles delete are being set up which lack any clear legal basis, which go beyond the minimum requirements for healthcare protection, and which contravene Article 20 of the GATT-TRIPs agreement [4].

4. Trademarks and Counterfeiting

The phenomenon 'counterfeiting' manifests itself on a worldwide basis. Counterfeits often originate in China, Taiwan – and South East Asia as a whole –, India, Brazil, South Africa, Israel, the Middle East, Turkey and the former communist bloc. In addition, there are cases in which counterfeit goods are manufactured in an EU country and are then sold inside and outside the EU.

The chemical industry is in some ways a special case: Pharmaceutical ingredients are produced in large quantities in third countries (India, China, Cyprus) and distributed *via* the EU to other third countries. The goods are re-declared, given new papers and marked as goods of European origin. In addition, medicines and crop protection products are fabricated illicitly in Spain, Italy, Greece, Cyprus and Turkey and imported into other EU countries under the guise of an apparently legal parallel import.

One of the major problems for combating trans-border piracy is the implementation of different types of protection in individual countries under different legal orders and with different procedural rules. Patent and design protection provide a good example of these differences, whereas it is easier in the trademark field.

A further problem is tracing counterfeits back to the original manufacturers. This is especially difficult with copies from Asia. Prosecution can only be successful if the plaintiff can produce actual products, proof of protection and the address of the manufacturer.

Many chemical companies face additional problems which stand in the way of effective defense against counterfeiting:

- Cost of acquiring and maintaining rights
- Incomplete information about the existing legal instruments
- Difficulty for customs to recognize copies on import
- Difficulties in tracing such cases to their source
- Problems of cooperation with the authorities in the country where the copy was manufactured.

All in all, it is a problem that the measures in place to combat counterfeiting take too long to be effective and are often unwieldy. The costs of prosecution are too high in some countries. It is also regrettable that courts give different interpretations to counterfeiting or piracy in individual countries.

5. Internet Domain Names

The Internet Domain Name System in general, but to a large extent also in the chemical and pharmaceutical arena, has reached such a high level in its development that business competition has heightened and global participation significantly increased. This has led to E-Business, a new form of doing business on the Internet. Trademarks and Domain Names play a key role in this context.

However, the Internet Corporation for Assigned Names and Numbers (ICANN) and other major intellectual property organizations from around the globe are still trying to solve a number of critical issues, namely to develop a structure and the procedural rules for this new form of intellectual property (including trademarks, copyright, and patents) as the fundamental components of meaningful commercial activity in the national, regional, and global realms in the fields of the Internet Domain Name System [5].

In spite of all the still existing difficulties, Internet Domain Names and E-Business are of very high importance for the global business of the chemical and pharmaceutical industry. The respective activities are clearly focused to the business-oriented use of Domain Names and the defense against the unauthorized use and registration of Domain Names by 'cybersquatters' and/or 'grabbers'. Trademarks and Internet Domain Names, if closely interlinked, will considerably contribute to generate value. Moreover, trademarks have proven to be one of the best tools against cybersquatting!

6. Perception of Trademark and Drug

Without any doubt, the chemical and specially the pharmaceutical market is a politically sensitive and emotionally charged area of economic activity. As described above, particular difficulties are attached to the use of trademarks, which are subject to special regulatory requirements. Nonetheless, good drug trademarks enjoy a special status amongst 'consumers', owing in particular to the high degree of differentiation provided by their mediation of the key message associated with a product. If a drug trademark is strategically managed and consistently 'recharged' with positive energy in the customer's consciousness, it is a highly potent value-adding factor. Despite all the challenges it faces, namely parallel imports, counterfeiting and Internet domain names, the trademark should thus retain its key role in the pharmaceutical market.

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[1] The 'Regulations on the Community Trade Mark' may be found at *www.oami.eu.int/en/aspects/reg.htm*.
[2] The Madrid System of International Registration of Marks may be found at *www.wipo.int/eng/madrid/texts.htm*.
[3] Information and rules on the 'EMEA Certificate of a Medicinal Product' may be found at *www.eudra.org/techdocs/technical/certif.htm*.
[4] The text of the TRIPs agreement may be found at *www.wto.org./eol/e/pdf/27.trips.pdf*.
[5] The ICANN rules for 'Uniform Domain Name Dispute Resolution Policy' may be found at *www.icann.org/udrp/udrp-rules.htm* and the WIPO 'Supplemental Rules' at *www.arbiter.wipo.int/domains/rules/supplemental.html*.