



*Original Contribution*

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## ACCOUNTING TREATMENT OF INTELLECTUAL PROPERTY IN THE PHARMACEUTICAL INDUSTRY

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### ABSTRACT

Intellectual property (IP) rights are not always reported on the company's balance sheet. This is caused by the fact that legal and accounting frameworks give a different perspective on intellectual property. In the pharmaceutical industry IP protection is a critical issue because new drug discovery is a lengthy and costly process. The aim of the paper is to provide an overview of the general, as well as the industry-specific forms of IP protection in the pharmaceutical sector and their accounting treatment under IAS 38 Intangible assets. For that purpose each one of them is separately discussed. Patents and trademarks are two of the main types of intellectual property rights and are used in all industries. On the other hand, SPCs, data exclusivity and market exclusivity are designed to provide additional protection particularly for the pharmaceutical sector. Despite their importance in both innovative and generic pharmaceutical industry, not all of these IP rights are being accounted for as intangible assets because they don't meet the recognition criteria set by IAS 38.

**Key words:** intangible assets, patents, generic drugs, IAS, IFRS, IP

Despite being the main economic resource in the "knowledge-based economy", IP rights are not always reported on the company's balance sheet. The reason for this is that legal and accounting frameworks give a different perspective on intellectual property. According to IFRS, IP rights fall under intangible assets but are recognized as such only if they meet the criteria set by IAS 38 Intangible assets (1). In knowledge-intensive industries this usually leads to a low book-to-market ratio and doesn't provide the investors with relevant information about the company's performance.

The general topic of intellectual property as an intangible asset has been previously studied in academic literature (Moerman and Van Der Laan, 2006 (2), Lev, Cañibano and Marr, 2005 (3), Roslender, 2004 (4), etc.). There are however some industry-specific forms of IP protection for the pharmaceutical sector that

need to be further discussed. These include Supplementary Protection Certificates (SPCs), marketing exclusivity, data exclusivity, etc. The aim of this paper is to provide an overview of these IP rights and their accounting treatment under IAS 38 Intangible assets. For that purpose each one of them will be separately discussed.

According to Moerman and Van Der Laan, 2006 (5) "whilst legal regimes seek to define IP as an intangible with particular qualitative characteristics such as inventiveness and novelty, accounting regimes seek to measure and quantify it according to the economic benefit that the intangible will accrue to an entity and subsequently capital providers." The disparity between the legal and the accounting treatment of IP is caused by the difference of the underlying assumptions – assets vs. rights, ownership vs. control, exclusivity vs. future economic benefits, etc.

From an accounting perspective IP rights are intangible assets that have received legal protection. Most of them are transferable, i.e. they can be sold, licensed or exchanged (either

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individually or with a related contract, asset of liability).

Under IAS 38 (6) intangible asset is an identifiable nonmonetary asset without physical substance. The three critical attributes of an intangible asset are: identifiability, control (power to obtain benefits from the asset) and future economic benefits (such as revenues or reduced future costs). An intangible asset can be recognized only if its cost can be measured reliably.

Most IP rights are in the form of marketing-related (trademarks, service marks, etc.), artistic-related (books, musical works, photographs, motion pictures, etc.) and technology-related (patented technology) intangible assets. However not all IP rights are recognized as intangible assets while on the other hand there are some similar intangibles that are not recognized as IP by law.

New technologies developed by the entity can receive legal protection by registering a patent or utility model. This is particularly necessary when the object of invention is obvious. In other cases – when the formulation or manufacturing process cannot be determined by analyzing and reverse-engineering of the final product – it is better to keep the knowhow a trade secret. In contrast to the patent which requires the invention to be made public and has a limited time scope, the IP protection that the trade secret provides, has no time limits and doesn't involve revealing any technological advantage. According to Bulgarian Competition Law (7) it can be enforced by non-disclosure agreements with the employees.

From an accounting perspective, patented or non-patented technology can be recognized as intangible asset if it meets the criteria set by IAS 38. It can be purchased, acquired in business combination or it can arise from an in-house research and development. The legal protection of the underlying product or process is not a requirement for asset recognition.

According to Lemley (8) intellectual property is often mistreated as just another species of real property with its strong right of exclusion. In his paper, he argues that IP is a unique form of legal protection, designed to deal with the public goods problem. It is an exception to the free competition and it should only be used to

encourage inventions, giving as little protection as possible.

In the pharmaceutical industry IP protection is a critical issue because new drug discovery is a lengthy and costly process. According to DiMasi et al. (9), the development takes from 10 to 15 years and the total R&D cost per new drug is estimated to be US\$ 802 million (in 2000 dollars).

Pharmaceutical manufacturers can be divided in two main groups – innovative and generic. The former invest millions of dollars in drug development while the latter usually “reverse-engineer” the original formulation after its patent has expired. Intellectual property in the pharmaceutical industry is a controversial issue in the modern society because both innovative and affordable medicines are needed. Generic medicines are identical or bioequivalent to the reference drugs and can be marketed once the patent protection on the brand name product has expired. They are safe, effective and their price is lower. According to European Generic Medicines Association (EGA) “on average, generic medicines are sold at prices from 20% to 90% less than the originator product.” (10). This makes them the key to ensure sustainable healthcare system in an ageing population. On the other hand, innovative therapy can provide better quality of life for a lot of patients. New drug discovery however costs millions of dollars which means that originator companies should be able to recoup their R&D investment.

Bulgarian pharmaceutical market is mostly generic - according to Bulgarian Generic Pharmaceutical Association (11) generic drugs constitute about 83.7% (by volume) and 56.2% (by value) of the market. The local manufacturers are specialized in the production of generics, as well, which means a small number of new drugs in development. The main form of IP protection used by Bulgarian pharmaceutical companies is trade mark registration. For the original medicines, patent protection is being used, along with the additional protection granted by marketing and data exclusivity. The development of generic drugs can also result in a patentable new technology.

*Patents* provide originator companies “with a limited term legal monopoly on their invention granting them the right to exclude all others

from the scope of protection offered by the patent.” (12) In her paper Gordon, 2003 (13) discusses several incentive-based theories underlying the patent system:

- the incentive to invent – suggests that a patent is granted to encourage inventions, because without the patent protection investors might not invest sufficiently in inventive activities;
- the incentive to disclose – the inventor should share his knowhow in order to receive exclusive rights to the invention, which is the teaching function of the patent system. This removes the possibility of duplicating research expenditures.
- the incentive to design around – once the technical data on the patented invention has been disclosed, competitors are able to circumvent the patent’s scope by inventing non-infringing substitutes. This may result in cheaper and more effective products and processes;
- the incentive to organize post-inventive activities (the prospect theory) – it focuses on how to make an invention useful.

According to Bulgarian Patent Law (14) patent protection is granted only to inventions that are novel, have an inventive step and are susceptible of industrial application. Patent term in Bulgaria is 20 years from the filing date. After that time the invention enters the public domain and can be used by anyone. According to an EGA Report (15) “due to a diminishing number of newly registered products and contracting product pipelines, originator companies may be tempted to unjustly prolong the patent monopoly of existing products. The result is known as the “evergreening” of a basic patent with the help of follow-on patents to keep generic competitors off the market. ... The consequence of this is often an extensive thicket or cloud of patents around a drug.” According to EGA “any pharmaceutical product is typically protected by 20-40 different patents on various aspects and properties of the product”. (16) The basic patent usually covers the active substance itself, while the follow-on patents’ claims are on the isomeric form of the drug, formulations, concentrations of dosage forms, etc.

According to the above mentioned EGA Report other patent strategies, used by the pharmaceutical companies, include:

- Multiple divisional patent applications – since proving that the patent is not valid is costly, pending divisional applications is a way to maintain the uncertainty around a patent and keep generic competition from entering the market because a patent could be granted any time.
- Claiming a pharmacokinetic effect without linking it to the formulation used to achieve that effect – this means the patent claims a result without providing the method of achieving it. Hence no other company can develop a rival product that has the same effect without infringing the patent even if the formulation is entirely different.
- Second and subsequent medical use claims (Swiss-type claims) – such patents should be granted only to protect new and inventive therapeutic application but in practice are given to new dosage regimes, new populations, etc.

Such patents should not be granted because they don’t claim true inventions and are used only to prolong the legal monopoly. Creating uncertainties about the scope of patent protection, they restrain the rival products from entering the market without encouraging real inventions. The usage of such strategies is easy to explain considering the amounts spent by innovative companies for research and development and the losses they incur after the generic product has been launched. In their paper Davidson and Greblov, 2005 (17), give a good example for such a case: after Schering-Plough’s Claritin patent has expired in 2002, as a result of generic drug competition, sales of Claritin by Schering-Plough declined from \$3.2 billion in 2001 to \$1.8 billion in 2002 and to \$0.37 billion in 2003.

Other elements of patent strategies used by pharmaceutical companies are defensive patents and patent litigation.

The accounting treatment of patents is determined by the way they are acquired – through a purchase, in a business combination or internally generated as a result of in-house research and development. In the innovative pharmaceutical industry, the filing of a patent application is usually in the early stages of the development process. The fact that the patent has been granted doesn’t indicate that the future development will be successful and marketing authorization will be received. This

means that at this point future economic benefits cannot be considered positive. Therefore such patents won't be recorded on the balance sheet because they don't meet the recognition criteria set by IAS 38 Intangible assets.

Purchased patents that are not intended to be used in the operating activities, like defensive patents, shouldn't be accounted for as assets because they are not expected to generate future economic benefits.

Litigation costs incurred to defend a patent in a law suit and annual fees should be charged to expense because they are only needed to maintain the patent.

A main problem in pharmaceutical IP protection is that there is a long time gap between the patent application and the marketing approval of the new drug which shortens the term of the legal protection.

According to a study by Henry Grabowski, 2000 (18) the effective life of the pharmaceutical patent is 11.7 years. This is the time between the market launch of the new medicine and the end of the patent term. Considering the importance of pharmaceutical research and innovation, Regulation (EC) No 469/2009 gives the holder of the basic patent the right to obtain a *Supplementary Protection Certificate* for medicinal products (SPC). It gives the same rights and is subject to the same limitations as the basic patent. In Bulgaria the SPC system is introduced with the Accession to the European Union. The certificate can be granted only once. According to Article 13 of the above mention Regulation it takes effect at the end of the lawful term of the basic patent. The term of the certificate equals the period which elapsed between the filing date of the basic patent and the date of the first marketing authorization, reduced by a period of five years. The duration of the certificate may not exceed five years from the date on which it takes effect. Also a six months pediatric extension of the certificate can be granted in which case the term may not exceed five and a half years (Article 36 of Regulation (EC) No 1901/2006).

From an accounting perspective the cost to obtain an SPC should be capitalized in the cost of the basic patent because it prolongs its useful economic life. Under IAS 38 the annual SPC fees should be expensed when incurred

because no additional economic benefit is expected to flow to the entity.

Bulgarian law, in accordance with Directive 2004/27/EC (Article 10), provides two forms of complementary protection of the intellectual property in the pharmaceutical industry – data exclusivity and market exclusivity.

*Market exclusivity* means that a generic product cannot be placed on the market until *ten years* have elapsed from the initial authorization of the reference product. This period can be extended to a maximum of eleven years if the marketing authorization holder obtains an authorization for one or more new therapeutic indications which have a significant clinical benefit in comparison with existing therapies. Since the effective patent life can be under ten years, this provision gives the originator product a legal monopoly for at least a decade.

*Data exclusivity* applies to the results of pharmaceutical and pre-clinical tests and clinical trials and it is not data protection. It means that generic manufacturers are not required to provide the results of these tests and trials if they can demonstrate that their product is a generic of a reference product which has been authorized for not less than *eight years*. Therefore no duplicative tests and trials will be required for drugs with well-established medicinal use, recognized efficacy and an acceptable level of safety. This is one of the main factors contributing to their lower price.

Only innovative drugs are subject to data and market exclusivity. The rights that these provisions grant ensure the legal monopoly of the originator company even after patent expiry. Nevertheless, they are not treated as assets because no expenditures have been incurred in order to obtain them and their cost cannot be measured.

Bulgarian law in accordance with Directive 2004/27/EC (Article 10) provides for an exemption to the rights conferred by patents and supplementary protection certificates. It is called "research exemption" and allows generic companies to conduct clinical trials for regulatory approval before the patent has expired. This shortens the time between the end of the data exclusivity and the launch of the generic product.

A specific problem in the pharmaceutical industry arises from the “orphan” medicines, i.e. drugs that treat or prevent rare conditions (i.e. condition affecting no more than 5 in 10 thousand persons). The cost to develop such drugs wouldn't normally be recovered by the expected sales of the product because the number of patients is small. Pharmaceutical companies should be encouraged to invest in research and development of “orphan drugs”. Regulation 141/2000/EC (Article 8) provides such an incentive - *market exclusivity*. It means that for a period of *ten years* authorities won't grant a marketing approval or accept another application for a marketing authorization for the same therapeutic indication, in respect of a similar product. This gives the company exclusive rights to manufacture and sell the drug that treats a given condition with almost no competition. The period may be reduced to six years if, at the end of the fifth year, it is established that the product doesn't meet the criteria set by the Regulation or is sufficiently profitable and market exclusivity is not justifiable.

Another type of IP protection, used widely in the pharmaceutical industry, is trade mark registration. Even though medicines should be prescribed by their therapeutic properties, a well-known brand name can diminish the negative effect of generic competition. Generic manufacturers can also register the trade names of their products. As far as over-the-counter (OTC) drugs are concerned, recognizable brand name and customer loyalty are very important and can be a source of a monopoly profit. Trade mark registration gives additional protection that is not limited in time like patents.

The accounting treatment of brand names depends on the way they have been acquired. Purchased trademarks (often with the underlying product rights) and those, acquired in a business combination, are recognized as intangible assets. Under IAS 38 internally generated brands, however, shouldn't be recognized as assets because the cost of their creation cannot be distinguished from the other business development expenditures.

In conclusion it needs to be said that patents and trademarks are two of the main types of intellectual property rights and are used in all industries. On the other hand, SPCs, data exclusivity and market exclusivity are

designed to provide additional protection particularly for the pharmaceutical sector. Despite their importance in both innovative and generic pharmaceutical industry, not all of these IP rights are being accounted for as intangible assets because they don't meet the recognition criteria set by IAS 38.

Another issue that needs further discussion is accounting treatment of IP licensing agreements. They have various terms and include external development of own intellectual property, collaboration agreements, cross-license agreements, etc. Common practices in the pharmaceutical industry are also mergers and acquisitions, the aim being to build a stronger patent portfolio. Acquisition accounting in this case is no different from other industries.

## REFERENCES

1. IAS Plus, International Accounting Standards, IAS 38 Intangible Assets, <http://www.iasplus.com/standard/ias38.htm>
2. Moerman, L.C. and Van der Laan, S., Accounting for Intellectual Property: inconsistencies and challenges, *Journal of Intellectual Property*, 11(4), 243-248, <http://ro.uow.edu.au/commpapers/104>, 2006
3. Lev, B., Cañibano, L., Marr, B., An Accounting perspective on Intellectual capital, *Perspectives on Intellectual Capital*, Oxford, pp. 42-55, 2005
4. Roslender, R. “Accounting for intellectual capital: rethinking its theoretical underpinnings, *Measuring Business Excellence*, 8 (1): 38-45, 2004.
5. Moerman, L.C. and Van der Laan, S., Accounting for Intellectual Property: inconsistencies and challenges, *Journal of Intellectual Property*, 11(4), 243-248, <http://ro.uow.edu.au/commpapers/104>, 2006
6. IAS Plus, International Accounting Standards, IAS 38 Intangible Assets, <http://www.iasplus.com/standard/ias38.htm>
7. Competition Protection Law, article 37, 27 November 2008
8. Lemley, M., Neukom, W. Property, Intellectual Property, and Free Riding, *Texas Law Review*, Vol. 83, p.1031-1033, 2005
9. DiMasi, J.A., Hansen R.W., and Grabowski, H.G. “The Price of Innovation:

- New Estimates of Drug Development Costs,” *Journal of Health Economics*, vol. 22, no. 2, pp. 151-185, March 2003
10. Affordable Generic Medicines Reduce Prices and Increase Access to Medicines, EGA Factsheet on generic medicines
  11. Trifonov, K., 2008 the best year for Bulgarian pharmaceutical market, *Pharmaceutical Bulletin of Bulgarian Generic Pharmaceutical Association*, 10 (2009)
  12. Patent-related Barriers to Market Entry for Generic Medicines in the European Union, European Generic Medicines Association, p. 5, 2008
  13. Gordon W.J., Intellectual Property, Working Paper Series, Law and Economics, Working Paper N03-10 (Chapter 28 of *The Oxford Handbook of Legal Studies*, Oxford University Press, p. 638-639, October 2003
  14. Patent and Utility Models Registration Law, last revised 20 July 2007, Article 6
  15. Patent-related Barriers to Market Entry for Generic Medicines in the European Union, European Generic Medicines Association, p. 12, 2008
  16. Generic Medicines, Data Exclusivity and Patents, EGA Factsheet on generic medicines
  17. Davidson L., Greblov G. *The Pharmaceutical industry in the Global Economy, USA*, p. 7, 2005,
  18. Grabowski, H.G. and Vernon, J.M. “Effective patent life in pharmaceuticals”, *Int. J. Technology Management*, Vol. 19, Nos. ½, pp. 98-120, p. 109, 2000