



“IP Management @ Universities” Istanbul, April 14 to 15, 2011 Albert Long Hall, BOGAZICI UNIVERSITY

Patent and Pharmaceutical Industry

Prof. Dr. M. Fethi Şahin

FARGEM

FARMASOTİK ARAŞTIRMA GELİŞTİRME MERKEZİ
SANAYİ VE TİCARET. A.Ş.

Patent and Pharmaceutical Industry

Prof. Dr. M. Fethi Şahin

When a basic patent of a drug substance expired any drug can be produced by other companies. Duration of Basic patent is 20 years. This Sentence creates many questions

One can say that Pharmaceutical Sector is number one in dealing with patents.



Basic Patent

The term "basic patent" is frequently used to refer to a pioneering type of patent, such as a patent for the first synthesis of a chemical. A basic patent may be considered to be any prior patent. An improvement patent is one which adds to the technology of the basic patent.



FARMASOTİK ARAŞTIRMA GELİŞTİRME MERKEZİ
SANAYİ VE TİCARET. A.Ş.

Patent and Pharmaceutical Industry

Prof. Dr. M. Fethi Şahin

R and D and pharmaceutical Sector

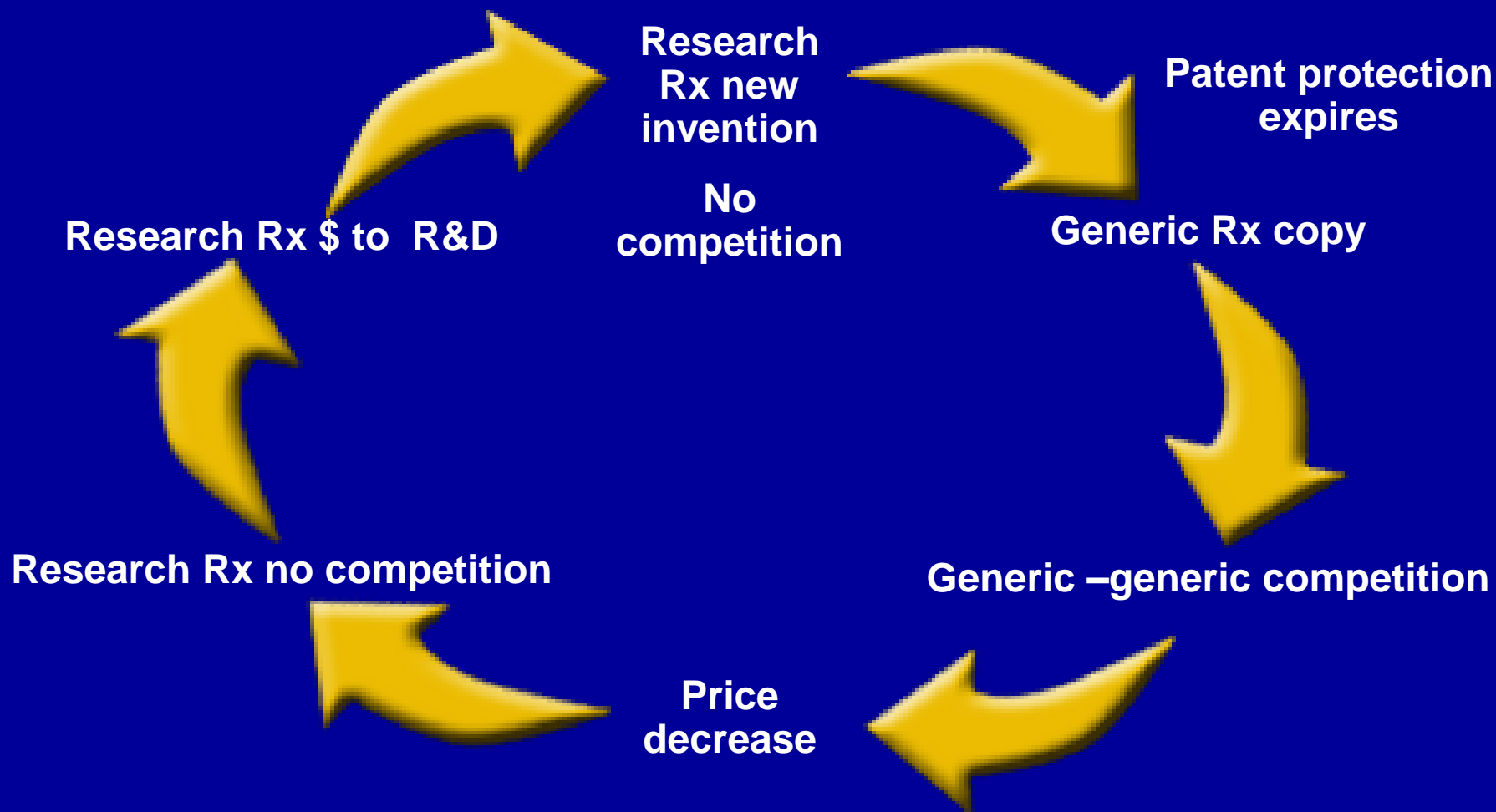


FARMASOTİK ARAŞTIRMA GELİŞTİRME MERKEZİ
SANAYİ VE TİCARET. A.Ş.

Patent and Pharmaceutical Industry

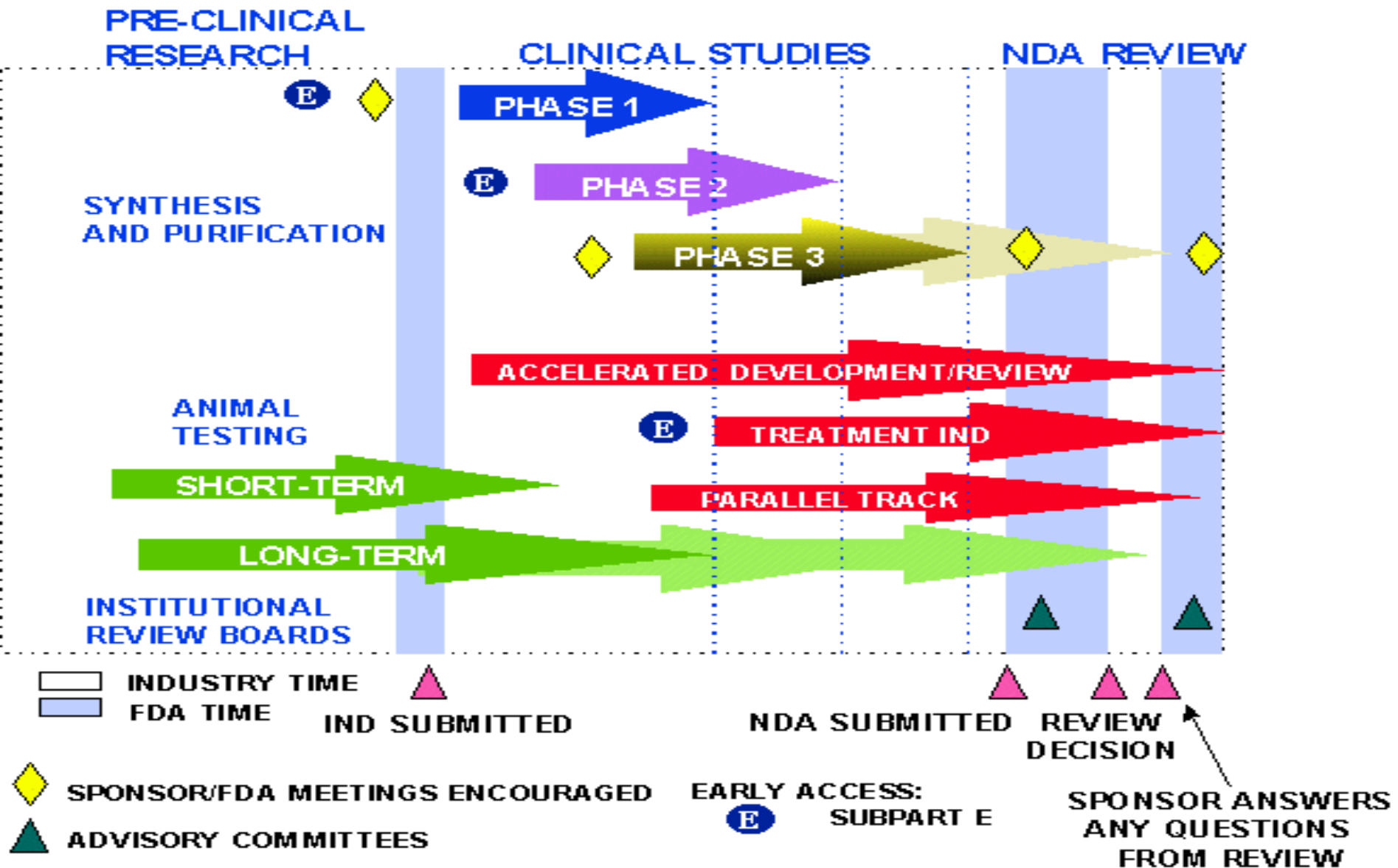
Prof. Dr. M. Fethi Şahin

Strong patent protection and free market forms beneficial symbiotic relation for both industries.



The New Drug Development Process

(Steps from Test Tube to New Drug Application Review)





What is Patent

- The term *patent* usually refers to an exclusive right granted to anyone who invents any new, useful, and non-obvious process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof, and claims that right in a formal patent application. The additional qualification *utility patent* is used in the United States to distinguish it from other types of patents (e.g. [design patents](#)) but should not be confused with [utility models](#) granted by other countries.

In the pharmaceutical, chemical and biotechnology industries the patent normally equals the product, and protects the extensive investment in research and clinical testing required before placing it on the market. Patent protection for chemical and pharmaceutical products is especially important compared with other industries because the actual manufacturing process is often easy to replicate and can be copied with a fraction of the investment of that required for the research and clinical testing.



The extensive cost required to produce a new pharmaceutical product has meant that private sector investment in pharmaceutical innovation has been disproportionately directed to products meeting the needs of patients in developed countries, particularly in the United States, which combines strong patent protection with a market free of price controls.



FARMASOTİK ARAŞTIRMA GELİŞTİRME MERKEZİ
SANAYİ VE TİCARET. A.Ş.

Patent and Pharmaceutical Industry

Prof. Dr. M. Fethi Şahin

Until the TRIPS Agreement (Agreement on Trade Related Aspects of Intellectual Property Rights) in 1994 many developing countries provided no patent protection for pharmaceutical products.



FARMASOTİK ARAŞTIRMA GELİŞTİRME MERKEZİ
SANAYİ VE TİCARET. A.Ş.

Patent and Pharmaceutical Industry

Prof. Dr. M. Fethi Şahin

National Patent Office

Every country with a patent system has a national patent office where claims of inventors may be made a matter of public record. As mentioned above, in many countries there is an examination before an inventor is given any substantive rights. In other countries patent claims are registered but detailed examination is delayed until a dispute over infringement arises.

The World Intellectual Property Organization (WIPO)

Headquartered in Geneva, WIPO is the specialized United Nations Agency that serves as the secretariat for administration of most of the global intellectual property treaties. It is the principal forum for negotiation of new patent treaties and the leading provider of technical assistance to developing countries in the field of intellectual property rights. WIPO was created in 1967 as the successor organization to the International Bureau for the Protection of Intellectual Property, which had been in existence since the 19th Century. WIPO Currently has 179 member states.



The World Trade Organization (WTO)

The World Trade Organization was established in 1994 in Marrakech following the successful conclusion of the Uruguay Round of Trade Negotiations. The predecessor to the WTO was the General Agreement on Tariffs and Trade (GATT). A key reform of the Uruguay Round was the Agreement on Trade Related Aspects of Intellectual Property Rights, known as TRIPS, codified as an annex to the treaty establishing the WTO.

It is important to recognize that the TRIPS Agreement was intended to create a more equitable system of international trade.



Patent

Examples of particular species of patents for inventions include biological patents, business method patents, chemical patents and software patents.

Some other types of intellectual property rights are referred to as *patents* in some jurisdictions: industrial design rights are called *design patents* in some jurisdictions (they protect the visual design of objects that are not purely utilitarian), plant breeders' rights are sometimes called *plant patents*, and utility models or Gebrauchsmuster are sometimes called *petty patents* or *innovation patents*. This article relates primarily to the patent for an invention, although so-called petty patents and utility models may also be granted for inventions.

Utility Model

A **utility model** is a statutory monopoly granted for a limited time in exchange for an inventor providing sufficient teaching of his or her invention to permit a person of ordinary skill in the relevant art to perform the invention. The rights conferred by utility model laws are very similar to those granted by patent laws, but are more suited to what may be considered as "incremental inventions". Terms such as "petty patent", "innovation patent", "minor patent", and "small patent" may also be considered to fall within the definition of "utility model".

Data Exclusivity

- *Data exclusivity" refers to the period during which the data of the original marketing authorisation holder relating to (pre-) clinical testing is protected. Accordingly, in relation to marketing authorisation applications submitted after 30 October 2005 for the applications filed in the framework of national procedures or 20 November 2005 for applications filed in the framework of the centralised procedure, 'data exclusivity' refers to the eight-year protection period during which generic applicant may not refer to the information of the original marketing authorisation holder and 'marketing exclusivity' refers to the ten-year period after which generic products can be placed on the market. However, in relation to marketing authorisation applications submitted before the above mentioned dates, the wording 'data exclusivity' refers to the six or ten-year protection period granted to the original MA holder before generic applicants can file their applications for marketing authorisation.«*
- **European Union**

DATA EXCLUSIVITY

Data exclusivity guarantees additional market protection for originator pharmaceuticals by preventing health authorities from accepting applications for generic medicines during the period of exclusivity.

EGA



FARMASOTİK ARAŞTIRMA GELİŞTİRME MERKEZİ
SANAYİ VE TİCARET. A.Ş.

Patent and Pharmaceutical Industry

Prof. Dr. M. Fethi Şahin

Pharmaceutical Industry

- Pharmaceutical Industry may be divided into two sections:
- Originator Companies
- Generic Companies

Patent system temporarily is operating in a very beneficial manner--for lawyers. For others, including inventors, engineers, scientists, and legitimate companies generating and/or using new technology, it is a costly, time-consuming quagmire. In some areas it is significantly slowing technological progress. What are the problems? Can they be solved via fine tuning, or should we consider a very different approach?

Conclusion

No creative people consider patents. They are not driven by the prospect of material rewards.

Without the patent companies will employ the creative people anyway.

The patent system is a time-wasting nuisance to engineers, generating tedious paper work and often putting restrictions on their activities.

For the employers patent is a defensive manner for their operation. Patent is a commercial good you can sell and by patents. Otherwise it is not stimulating invention.



Conclusion

Sometimes patent can be used to hamstring actual or potential competitors by denying their licenses

Actually Patent in pharmaceutical sector prevents improvements. Therefore the contemporary patent system must be rewritten in the future.

