

Data Exclusivity: Encouraging Development of New Medicines

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Data Exclusivity

- **Obtaining a marketing approval for a new medicine requires pharmaceutical companies to conduct extensive chemical, pharmacological, toxicological and clinical research and testing.**
- **The average cost of such studies is more than 1,000 million US \$, and takes up to 10 to 15 years to be completed.**
- **The data generated by such work, while proprietary to the pharmaceutical companies, must be submitted to the regulatory authorities of countries around the world such as the US Food and Drug Administration (FDA) and the European Agency for Evaluation of Medicinal Products (EMA), in order to obtain market approvals for the new drugs.**



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Data exclusivity – a fully qualified form of intellectual property

- **This concept was recognized internationally in the mid 1990s:**
 - ▶ **by the North Atlantic Free Trade Agreement (NAFTA - art. 1711)**
 - ▶ **the WTO agreement Trade Related Aspects of Intellectual Property Rights (TRIPs - art. 39.3).**

- **Data exclusivity is an intellectual property right**
 - ▶ **Recognized as such by the WTO TRIPs Agreement**
 - ▶ **Independent right from patents: separate and parallel sections in Part II of TRIPs Agreement**



Patent Protection versus Data Exclusivity

Patent Protection

- ▶ Provides incentive for discovery and development of innovative drugs (compounds), processes formulations, uses etc
- ▶ “Social contract” between innovator and society: government provides period of exclusivity to innovator in exchange for **disclosure of invention** so that science can move ahead

Data Exclusivity

- ▶ Derived from “**considerable effort**” needed to demonstrate safety, quality and efficacy of innovative drugs to regulatory authorities
- ▶ Not a social contract: rather, a limitation on the government’s ability to use an individual’s proprietary data in order to “**protect against unfair commercial use**”



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Patent Protection versus Data Exclusivity

Patent Protection

- ▶ Not possible to **copy the product** during the life of the patent
- ▶ Infringement (legal) action possible
- ▶ Royalties in case of compulsory license

Data Exclusivity

- ▶ Not possible to **use the same data** but it does not legally prevent other companies from generating their own registration data.
- ▶ Only administrative actions or unfair competition actions possible
- ▶ No pay-back provisions in the case of compulsory license



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Both Forms of Intellectual Property Protection are necessary to secure the legitimate “**return on investment**” for the pharmaceutical industry because

CONTINUING PROGRESS AND INVENTING NEW LIFE-SAVING DRUGS WOULD NOT BE POSSIBLE WITHOUT A PROPER RETURN ON INVESTISSMENT



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Patent Protection versus Data Exclusivity

- Does data exclusivity extend commercial protection beyond the term of patent?
 - ▶ Patent protection:
 - ┌ 20 years from the day of the **drug discovery** and possibility to extend the patent term by an additional period of up to 5 years via PTE or SPC's
 - ▶ Data exclusivity for the majority of the drugs (NCE):
 - ┌ 5 (for example US) to 10 years (EU) from the day of the **drug registration**
- Data exclusivity may affect the overall period of market exclusivity when:
 - ▶ the development period of a given drug is particularly long
 - ▶ the drug does not enjoy an « one-way » patent protection



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The rimonabant case



● Patent Protection

- ▶ The patent family covering the genus claims priority of June 1992
- ▶ The patent family covering rimonabant *per se* claims priority of December 1993. Patents are granted in 41 countries.

● Submissions to Regulatory Authorities

- ▶ EMEA April 2005 - Approval granted in June 2006
- ▶ FDA April 2005 - Approval not yet granted



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The rimonabant case

India

● Patent Protection

- ▶ The **active ingredient** *per se*, rimonabant, is **not** protected in India.
- ▶ Patent applications covering the **formulation** of Acomplia™, stable polymorphs, and therapeutical uses of rimonabant, although filed since 1998, are still under examination.

● On May 2007 launch of Slimona before Acomplia

- ▶ Based on which clinical data?
- ▶ Fair commercial use?





The rimonabant case - Sanofi-Aventis data are used for Slimona

Slimona
Rimonabant 20 mg Tablet

Zydus
dedicated to life

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Endocannabinoid System.

The Endocannabinoid (EC) system is a physiologic system, acts centrally as well as peripherally, and plays a key role in regulating body weight and metabolic processes. The EC System also plays a role in tobacco dependence.

Endocannabinoids (ECBs), are the chemical messengers of the EC System, which bind and activate the cannabinoid (CB) receptors. There are currently two known subtypes of cannabinoid receptors namely, CB1 and CB2.

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graph TD
    A["Endo cannabinoids :  
(Endogenous Agonists of Cannabinoid Receptors)"] --> B["• Are produced as needed  
• Activate cannabinoid receptors locally  
• Are metabolized rapidly"]
    B --> C["Cannabinoid receptor type 1 (CB1)  
(Most widespread CB receptor)"]
    B --> D["Cannabinoid receptor type 2 (CB2)"]
    C --> E["Brain Adipose Tissue Muscle Liver GI Tract"]
    D --> F["Immune System"]
```



Thank you
for your attention



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Slimona (Generic Acomplia) - 20mg (14 Tablets).htm



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