MARKET EXCLUSIVITY AND PATENT PROTECTION – A REGULATORY PERSPECTIVE

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PURPOSE

To provide a regulatory perspective on market protection for drugs

AGENDA

- Market Protection for Drugs
  - Exclusivity – Market Protection vs Data Exclusive
    - US and EU Perspective
    - Additional exclusivity protections
- Intellectual Property
  - Patent Protection
- What is the difference between Patent Protection and Marketing Exclusivity
- Conclusion

WHY PATENTS AND EXCLUSIVITY

- Protecting the intellectual property of new drugs is complicated but essential for pharmaceutical companies.
- Both Patents and Exclusivity create period during which a new drug is protected from direct competition.
  - create a favorable environment to encourage drug development.
  - promote a balance between new drug innovation and generic drug competition
- Allows companies to recoup the cost of investment in producing data required by the regulatory authority

MARKET PROTECTION FOR DRUGS

- Market Protection for Drugs
  - Market vs Data Exclusivity
    - US FDA
    - EU EMA
  - Intellectual Property
    - Patents
    - Trademarks
    - Copyrights
    - Trade Secrets

TYPES OF EXCLUSIVITY – US FDA

- **Filing Exclusivity**

= Period of time during which a Company cannot submit an application by cross-reference to the data in support of another marketing authorization

ie no submission of Abbreviated NDA / 505(b) (2) applications

- **Approval Exclusivity**

= Period of time during which a Company cannot gain approval for an application by cross-reference to the data in support of another marketing authorization

ie no approval of Abbreviated NDA / 505(b) (2) applications

US: 5 YEAR FILING EXCLUSIVITY FOR NCE

The first pharmaceutical company to receive NDA approval for a drug product containing a new chemical entity (NCE) is entitled to a 5-year period of FDA ***filing exclusivity.***

What is a NCE ?

New chemical entity (NCE) is a drug that contains no "active" moiety that has been approved in another NDA

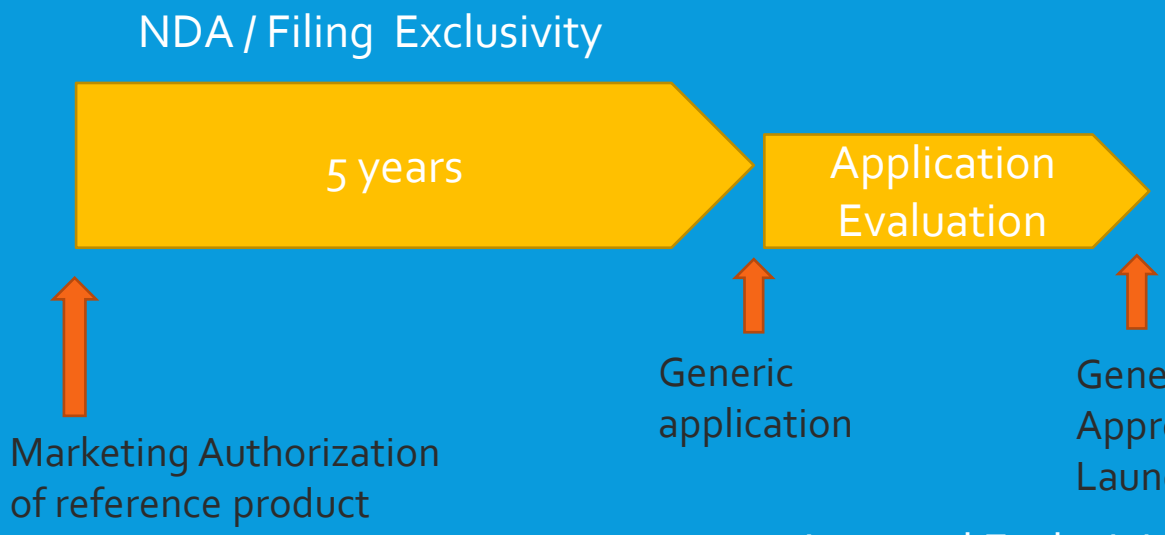
An "active moiety" is defined in FDA's regulations at 21 C.F.R. § 314.108(a) to mean "the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance."

US: 3-YEAR DATA EXCLUSIVITY

"[I]f a supplement to an application approved under subsection (b) . . . contains reports of ***new clinical investigations*** (other than bioavailability studies) ***essential to the approval*** of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b)"

- Section 505(j)(5)(F)(iv) of the FD&C Act

US FDA:



First NDA approval for a drug product containing a NCE is entitled to a 5-year period of FDA filing exclusivity

- New Clinical indications for approved products
- Formulations
- Dosing regimens
- Patient populations
- OTC Switch

TYPES OF EXCLUSIVITY – EU EMA

- **Data Exclusivity**

= Period of time during which a Company cannot submit an application by cross-reference to the data in support of another marketing authorization

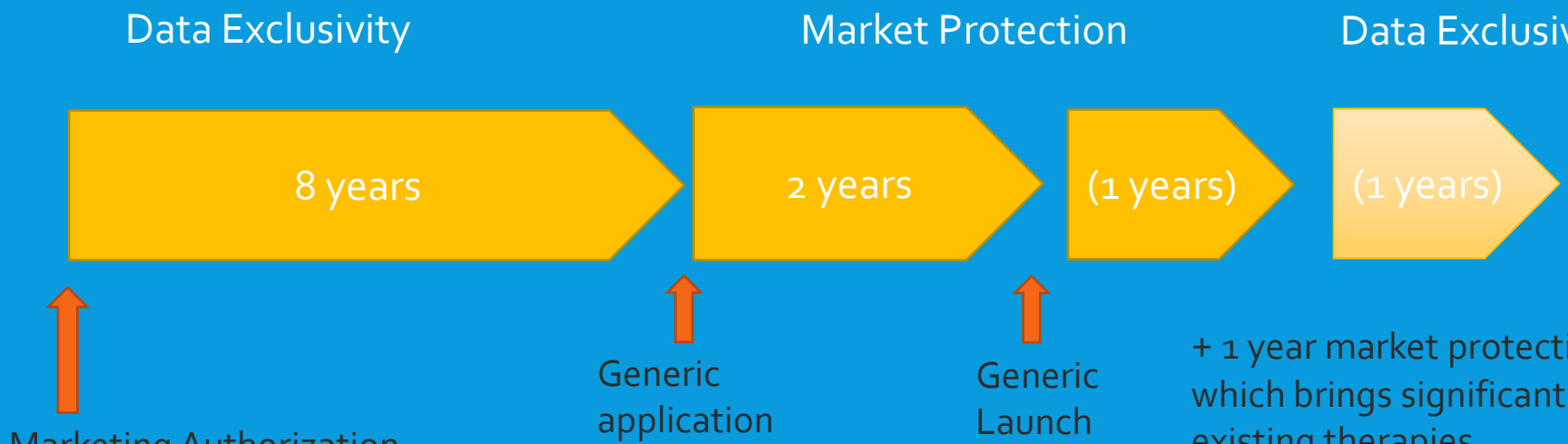
ie generics, hybrids, biosimilars applications cannot be validated by the Agency

- **Market Protection**

= Period of time during which a generic, hybrid or biosimilar cannot be placed on the market, even if the medical product has already received a marketing authorization

ie Approved generics, hybrids, biosimilars can not launch

EU EMA:
8 + 2 (+1) EXCLUSIVITY FORMULA



+ 1 year market protection for new therapeutic indication which brings significant benefits in comparison with existing therapies

+ 1 year data exclusivity for a new therapeutic indication for a well established substance, provide that significant pre-clinical or clinical studies were carried out

+ 1 year data exclusivity for a change in classification of a medicinal product on the basis of significant pre-clinical test or clinical trials.

EU: EXTEND MARKET PROTECTION AND DATA EXCLUSIVITY

+ 1 year market protection for new therapeutic indication which brings significant benefits in comparison with existing therapies

+ 1 year data exclusivity for a new therapeutic indication for a well established substance, provide that significant pre-clinical or clinical studies were carried out

+ 1 year data exclusivity for a change in classification of a medicinal product on the basis of significant pre-clinical test or clinical trials.

EU: *IS IT A NEW INDICATION?*

SmPC guideline [Sep 2009], Section 4.1 Therapeutic indications '*The indication(s) … should define the **target disease** or **condition** distinguishing between treatment (…), prevention (…) and diagnostic indication. When appropriate it should define the **target population** ….'*

- New target disease
- Different stages or severity of a disease
- Extended target population for the same disease
- Change from the 2nd line to 1st line treatment
- Change from combination therapy to monotherapy, or from one combination therapy to another
- Change from treatment to prevention or diagnosis of a disease
- Change from treatment to prevention of progression or to prevention of relapses of a disease
- Change from short-term treatment to long-term maintenance therapy in chronic disease

EU: *WHAT ARE THE EXISTING THERAPIES?*

Satisfactory methods of diagnosis, prevention or treatment of the disease.

These include:

- Authorised medicinal products
- Non-pharmacological approaches
- Other 'state-of-the art' therapeutic methods for the indication

Does not include: Off-label use of medicinal products

EU: WHAT IS SIGNIFICANT CLINICAL BENEFIT ?

➢ **Improved efficacy**

- *Same level of evidence needed to support a comparative efficacy claim for two different medicinal products. Direct comparative clinical trials preferred*

➢ **Improved safety**

The relative safety profile will have to be globally assessed compared to existing therapy(ies), preferable through comparative trial(s). No important reduction in benefit should be seen

➢ **Major contribution to patient care**

- *New mode / route of administration*
- *Treatment alternative*
- *Response different from other treatments in a substantial part of the target population*

ADDITIONAL EXCLUSIVITIES: PAEDIATRIC

- To study drugs in children for new products or authorized products with new indication, pharmaceutical form and route of administrations

- US : Final ANDA / 505(b)(2) approval delayed for 6 months

- EU:

	Obligations	Incentive
New Medicinal Product / On Patent and Authorized Medicine	Paediatric Investigation Plan or Waiver	6 months extension
Orphan Medicine	Paediatric Investigation Plan or Waiver	2 additional years of market exclusivity
Off Patent Medicine	None (voluntary PIP possible for PUMA)	8 + 2 years of data protection

ADDITIONAL EXCLUSIVITIES: ORPHAN DRUGS

- **US :** Orphan Drugs are defined as "those intended for the safe and effectiveness treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than **200,000 people in the US**
- **EU**: ODs are defined as "those intended for diagnosis, prevention or treatment of diseases that affect fewer than **5 in 10,000 people in Europe**

US	EU
7 year Data Exclusivity	10 year Market Exclusivity

- Protection and/or Market Exclusivity puts Orphan Drugs on level playing field
  - Most companies usually focus on potential therapies with the highest likelihood of generating a good financial return
  - This has meant that potential therapies for rare diseases for life-threatening conditions are at disadvantage early on
  - Conventional approaches to drug development are often not feasible for rare diseases, which offer not only small markets but also small populations for participation in clinical trials

INTELLECTUAL PROPERTY (IP)

- According to World Intellectual Property Organization, Intellectual Property is creations of the mind — inventions, literary and artistic works, symbols, names, images, and designs used in commerce.
- Intellectual property (IP) can be include:
  - specific manufacturing process
  - plans for a product launch
  - chemical formula/proprietary formulas
  - "intangible proprietary information"
  - inventions (products and processes),
  - ideas
- For many pharmaceutical companies, IP can be more valuable than any physical asset

FOUR CATEGORIES: INTELLECTUAL PROPERTY

- Patents
- Trademarks
- Copyrights
- Trade secrets

WHAT IS A PATENT ?

A Property Right:

- Right to ***exclude others*** from making, using, selling, offering for sale or importing the claimed invention
- Limited term: In most countries, patent can last for 20 years
- Territorial: protection only in territory that granted patent; NO world-wide patent

WHY PATENT PROTECTION

- Protect Inventions
- Encourage Inventions
- Promote commercialization and application of invention
- Accelerate the commercialization of invention to the whole society

A patent is a set of exclusive rights granted by an agency to an inventor for a limited period of time in exchange for detailed public disclosure of an invention

PATENT PROTECTION VS EXCLUSIVITY?

- Patents and exclusivity work in a similar fashion but are distinctly different from one another.
- Patents are granted by the patent and trademark office anywhere along the development lifeline of a drug and can encompass a wide range of claims.
- Exclusivity is protection granted by a regulatory agency upon approval of a drug and can run concurrently with a patent or not.
- Exclusivity was designed to promote a balance between new drug innovation and generic drug competition.

CONCLUSION

- There are some pathways to protect the development of your drug
  - Market / Data Exclusivity with additional protections for Paediatric and Orphan Drugs
  - Patent Protection
- These protections allows companies to recoup the cost of investment in producing data required by regulatory authorities, and promote a balance between new drug innovation and generic drug competition

Terima kasih

Thank you