Trends in IP strategy for young companies – viewed from a larger company

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Agenda

- General Information on Intellectual Property
- IP strategy for young Biotech companies
- How can young Biotech companies become more attractive for their “customers”?

General Information on Intellectual Property

Intellectual Property

- **Five major kinds of Intellectual Property**
  - Patent
  - Copyright
  - Industrial Designs
  - Trademark
  - Trade Secret
- **Like real Property**
  - It can be bought, sold, licensed, exchanged, given away
  - The owner can prevent unauthorized use

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  - Industrial Designs
  - Data exclusivity/Market protection
  - Trademark
  - Trade Secret
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Patent

- Patenting provides a strategy for protecting inventions without secrecy
- A patent grants the right to exclude others from making, using, and selling the invention for a limited term of 20 years from application filing date in most of the jurisdictions
- To get a patent, an inventor must disclose the invention fully so as to enable others to make and use it
- Patents thus facilitate transfer of technology to the private sector by providing exclusive rights to preserve the profit incentives of innovating firms
- Patent term restoration allows extension of patent life in order to restore some of the time lost in the process of satisfying the requirements for regulatory approval (max 5 years – patent life cannot exceed 14 years after product approval)

Data exclusivity / Market protection

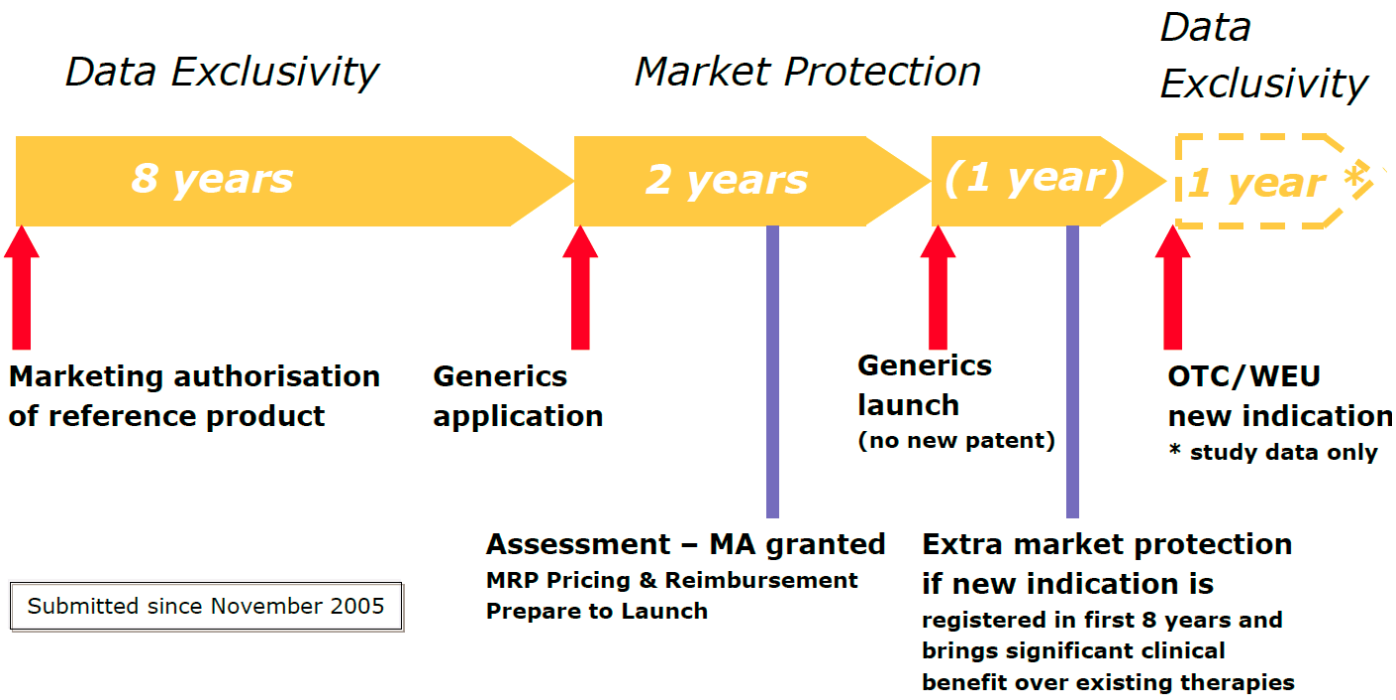
- The rationale for granting data and market protection is to compensate the innovator company for the investment it has put into developing the new medicinal product
- It aims at pushing developers to generate the data required to obtain a marketing authorization
- Data exclusivity is a period of time during which a competing company cannot cross-refer to the data in support of another marketing authorization

=> generics, hybrids, biosimilars cannot be approved by the EMA or FDA

- Market protection is a period of time during which a generic, hybrid or biosimilar cannot be placed on the market

Data exclusivity / Market protection

8+2(+1) exclusivity formula



EMA 2005-2006

Supplementary Protection Certificate

- Valid patent covering the active ingredient in the concerned country
- A market authorization issued by the health authority of the concerned country (FDA, EMEA, Swissmedic)
- The SPC is valid from the expiry of the maximum period of the patent protecting the active ingredient and prolongs the protection of up to 5 years

Patent life - Data / Market protection

- Both Europe and USA have similar incentive systems which aim at pushing investments until late stage development
- In 2006, patent term restoration and exclusivity accounted for approximately 39 percent of the total sales revenue of +$100 billion for the 40 top-selling drug products

⇒ It often can trigger the profitability of projects by increasing the revenue time frame

⇒ Is it relevant for Biotech activities? (to be discussed later)

Intellectual Property in Biotechnology field

Biotech Patenting, Introduction

- **Why is it such an important (difficult) issue to obtain IP protection in the Biotech sector?**
  - Life Sciences are not exact
  - Developing new drugs takes years/decades (close to patent life)
  - Very intensive research at very high cost for R&D (range between few hundred millions to a billion to bring a product on the market)
  - The competition is tough and not “fair” (small biotechs have less cash to invest than big pharmas)
  - In most cases, IP represents the only assets for small companies

Must Inventions be protected early?

- Inventions must be protected prior to any external solicitation (investors, partners, etc…)
- Balance between risk of disclosure and risk not to be the first
- Patent life/protection will start from the application date (20-25 years of protection vs 12-18 years of development)
- Biologics (12-15 years of market exclusivity) and SCE could be managed differently but IP will be required prior to discussion with partners

Must Inventions be protected broadly?

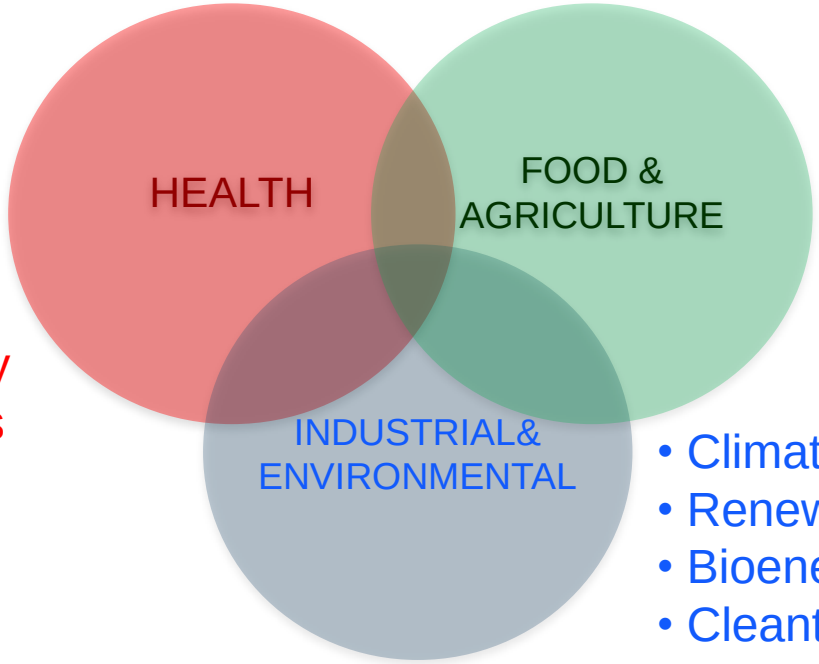
- Given the costs involved, Biotechs need to take care when deciding in which countries parallel IP applications should be made
- WW market versus major markets – Emerging markets?
- Biotechs must consider those countries in which:
  - the product will be sold (or where revenues will be highest/most significant)
  - major competitors are based
  - major supplier firms are based
  - product piracy can be expected
  - in addition to the country of origin
  - Your partner will expect return on their investment

How can young Biotech companies become more attractive for their “customers”?

Biotechnology field

- High revenue potential
- Global revenue of Biotechnology was about $ 80 billion in 2007, $100 billion in 2011, and expected to reach $150 billion in 2015
- The US market accounts for 75% of global revenue and 80% of R&D investment
- During the last 15 years, biotechnology companies launched more than 200 new drugs and vaccines

- Drugs
- Vaccines
- Diagnosis
- Gene therapy
- Biomedicines



- Animal biotechnology
- Agriculture biotechnology
- Sustainability

- Climate and sustainability
- Renewable technology
- Bioenergy
- Cleantech

Pharmaceutical Industry Realities (1/3)

End of blockbuster era – Large decrease of revenue

- Blockbuster drugs totaling up to US$120b in annual sales are set to lose patent protection over the coming years (IP is a trauma for Pharma!)
- These blockbuster drugs that once contributed US$5b or US$6b may generate no more than US$50m in annual revenues (100 X decrease)
- Current drug discovery pipelines of Pharma companies will not be able to rapidly replace them
- Evolution of the Pharmaceutical field with personalized medicines will split the market size into even smaller markets (one drug, one bug concept)

Pharmaceutical Industry Realities (2/3)

End of blockbuster era – Short term solutions

- Many companies are addressing this situation by aggressively cutting costs and reducing their fixed-cost structures
- Major layoffs in Pharma: the top 10 pharma layoffs amounted to 26,500 jobs in 2011, more than 34,600 in 2012, then nearly 27,900 in 2013
- Patent expirations provide significant new opportunities for generic pharmaceutical companies, many of whom are aggressively expanding their operations through acquisitions (Novartis, Actavis, TEVA, DRL etc…)
- M&A to reinforce or consolidate portfolios (solves one immediate problem but does not ensure the sustainability)

Pharmaceutical Industry Realities (3/3)

End of blockbuster era – Long term solutions

- Innovation combined with a medical return (diagnostics for improving outcome instead of splitting)
- Accepting to move onto multidrugs/blockbuster concept
- Let innovation come from the best innovators (“small and beautiful”)
- Support and accompany innovations without destroying creativity/reactivity
- Spend less / produce more
- Develop reimbursed drugs and not approved drugs

Debiopharm - business model

1 Drug Project

Licensor :
Academic Biotech
Start-up Pharma

Innovation

2 Creative Drug Development

Clinical Strategy
Market Access
Project & Lifecycle Management

3 Patients

Licensee :
Mid-size & Big Pharma

Commercialization

Debiopharm - business model

Requirements of Licensor

- Innovation considering market access (licensing deal terms aligned with this crucial issue)
- Existing IP with potential improvements (product patent, patent of use, life cycle management)
- All indications/applications
- Broad territory protection (avoid split – exception if Pharma)
- Depending on the field, data/market protections can be an add-on (Biologics, GAIN act)

Requirements from Licensee

- Innovation considering market access
- Existing IP with potential improvements (life cycle management)
- Broad territory protection
- Depending on the development stage:
  - Data/market protection can replace IP (product must be registered)
  - All indications or specific indications

Biotech companies - business model

1 Drug Project

Licensor :
Academic Biotech
Start-up Pharma

Innovation

2 Creative Drug Development

Clinical Strategy
Market Access
Project & Lifecycle Management

3 Patients

Licensee :
Mid-size & Big Pharma

Commercialization

Biotech companies

Biotech “must have”

Requirements of Licensor (if not originator)

- Innovation considering market access
- All indications/applications
- All territories
- Existing IP with potential improvements (product patent, patent of use, life cycle management)

Requirements from Licensee

- Innovation considering market access
- All indications/applications
- All territories
- Existing IP with potential improvements (life cycle management)
- Broad territory protection
- Not applicable:
  - Data/market protection can replace IP (data not sufficient)
  - Specific indications (too risky to allow parallel development)

Contact information

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