

# IPR at an innovative SME

*Best Practices*

Emil Pot

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ActoGeniX

# ActoGeniX NV

- Biopharmaceutical company founded in 2006 in Ghent (BE) as a university start-up, raising 46 M Euro.
- Small but experienced team (21 employees) with all key competencies available in the company for research, preclinical and clinical development
- Based on a unique and high tech platform and for oral delivery of biologics addressing GI, mucosal, and immunological diseases - **ActoBiotics™**
- 115 granted patents and 48 pending patent applications covering the ActoBiotics platform technology and broad claims granted in US, EU and Japan



# IP important element of innovative SME

- Technology platform
- R&D portfolio & strategy
- **IP position**
- Freedom To Operate
- Business development strategy
- Team

# SMEs and their contribution to economic growth

## - some facts -

- SMEs represent 99% of all enterprises and two-thirds of employment; they are important drivers of job creation (OECD 2010)
- In the US, small and young firms generate a disproportionate amount of all new jobs; while **start-ups** represent only 3% of total employment, they **account for almost 20% of total new job creation** (haltiwanger et al. 2010)
- Innovative SMEs have the potential over the long-term to contribute substantially to improvements in productivity, competitiveness, and technological progress in their sector and the economy as a whole (Ohler *et al.* 2007; OECD 2010; Pederzoli *et al.* 2011)

# IP challenges for SMEs

- In-house expertise of IP
  - correct understanding of IP
  - IP coverage of future product strategy
  - territories to file and validate patents
  - redundant IP
  - instruct patent attorneys adequately
- Financial Resources for filing and validation of patents
- Law suits on IP; infringement cases and 'patent trolls'

# SME decision: appoint IP Manager

- Innovative SMEs need to appoint an IP Manager
  - Interact between R&D and Business Development
  - Determine IP filing strategy of the company
  - Identifying competitors and competitive products/technology
  - Monitoring patent prosecution

# Interacting R&D and Business Development

- R&D and BD are 'communicating vessels' in determining SME's future product/technology strategy
- IP Manager should be part of discussions between R&D and BD regarding research activities/results and business opportunities
- IP strategy should be focussed on protecting SME's future products/technologies

# Determine IP filing strategy of the company

- IP filing strategy should be tailor made to SME and its technology
  - Consider early filings to safeguard 'first to file'
  - Review and internally discuss Search Report; reconsider further prosecution into international phase (PCT)
  - Identifying competitors and competitive products/technology
  - Consider entering into national/regional phases after PCT phase
  - Costs versus territorial coverage (after PCT-phase); minimal filing in EU/US
  - File in countries where your competitors are and the market is



# Consider early filings to safeguard 'first to file'

- Consider to obtain earliest possible priority date by 'provisional' patent filing
- Filing at 'no cost' is possible at EPO, in order to obtain a priority date; recommended in case of anticipated public disclosure or patent filing by competitors
- On-line filing possibility at EPO

# Review and internally discuss Search Report

- Choose right ISA for Search; EPO & USPTO are good options
- Search Report provides good view on patentability of invention and scope of protection
- Internal review if scope of protection is (still) matching future product/technology strategy

# Identifying competitors and competitive products/technology

- Search report may identify (unknown) competitors and similar or closely related products/technology
- Search may provide additional technological know how for the R&D team and create new opportunities
- Feedback and internal discussion with R&D and BD necessary

# Important factors to consider for continuing IP prosecution

## Subject matter of patent:

- Composition of matter; product claim
- Process claim

## Purpose of patent:

- protecting future product or purely defensive patent
- near-term or long-term use
- low or high probability of success (scientifically & commercially)

## Patentability of patent:

- scope of protection expected
- enforceability

# Patent Cost: PCT nationalisation vs market size

- Mimimum : US, EP (~70% market)
- Small : US, EP, JP (~80% market):
- Large : US, EP, JP, CN, CA, IN, AU (~90% market):
- Maximum : US, EP, JP, CN, CA, IN, AU, BR, MX, KR, RU, IL, NZ, SG, ZA (~93% market)



but in any event, file in the countries where your competitors are located

# Monitoring Patent Prosecution & Patent Port Folio

- IP Manager should closely monitor patent prosecution and instruct the patent attorneys; IP Manager is the only one who knows what protection is sought in view of SME's product/technology strategy
- Continued interaction with R&D and BD teams is required from the IP Manager in order to align patent prosecution and scope of the patent claims with SME's product/technology strategy
- Choose the right moment to abandon Patent Rights and avoid further costs in case of:
  - No further commercial interest in the claimed product/technology
  - Patentability is weak
  - Enforceability is difficult

# Financial Resources for filing and validation of patents

- Consider on-line filing at EPO, which can be done by the IP Manager itself at a low cost
- Providing sufficient sales income from the product/technology before expensive national/regional phase starts
- Lobbying at governmental level for IPRs that are available and enforceable at reasonable cost by SMEs; some national bodies provide funding for the initial patent filings

# Law suits on IP; infringement cases and 'patent trolls'

- SME's should avoid litigation at all times, if possible; negotiating with the opponent is preferred
- Obtain adequate advice from professional lawyers how to avoid litigation
- Perform patent validity search of the 'alleged' patent that could be infringing



THANK YOU

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