

Lundbeck's view on the EU IP systems



Agenda

- The Innovative Pharmaceutical Industry and why IP is so important for Lundbeck
- Lundbeck's wish list for improved IP systems
- Conclusion



The Innovative Pharmaceutical Industry

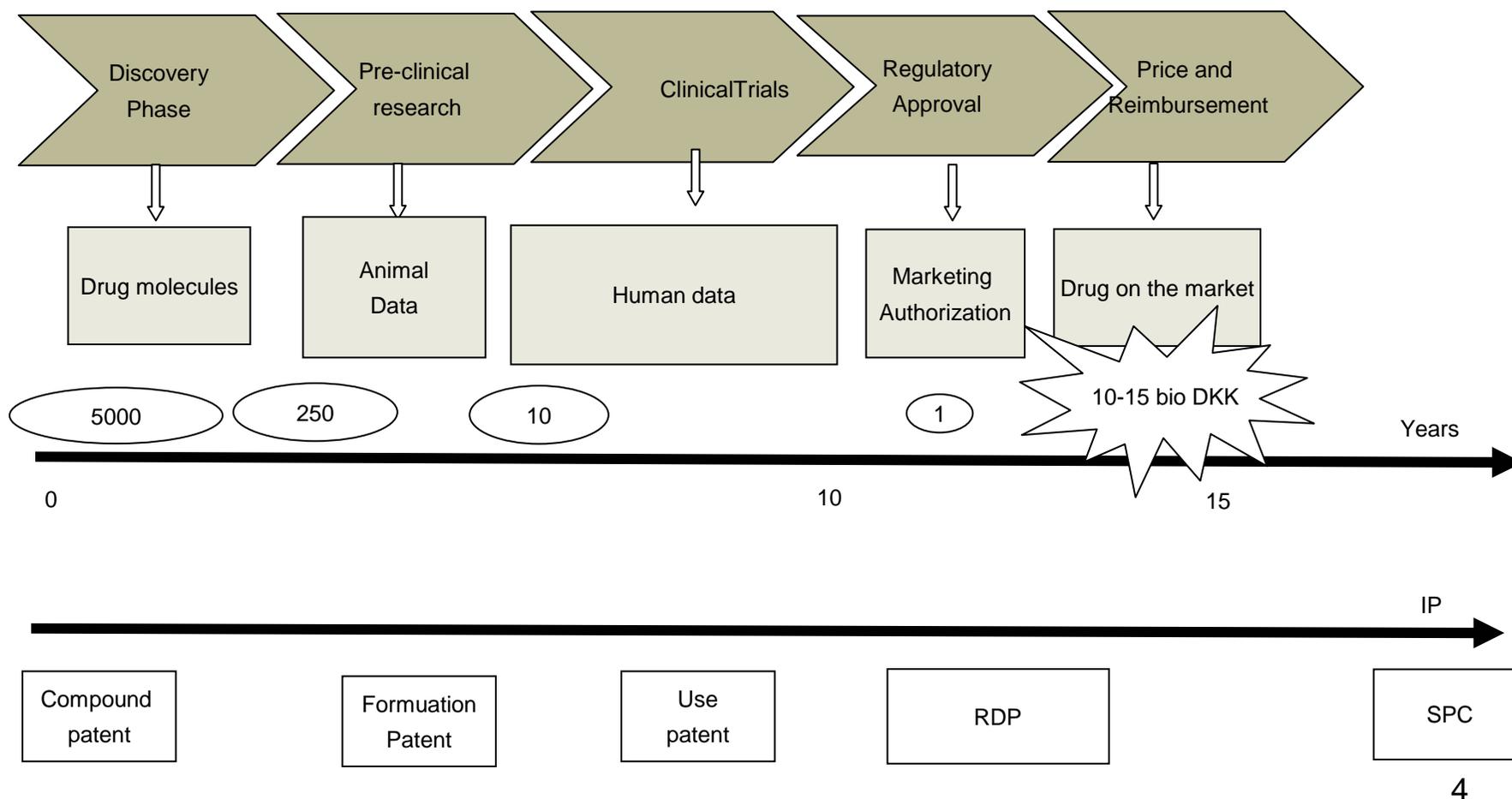
- Our business model is based on research and development to provide improved drugs and therapies

- Our main challenges are
 - A complex and time-consuming path from idea to market
 - Huge development costs
 - A very low probability of success
 - Society's ability and willingness to pay for innovation

- An efficient and high quality IP system is **FUNDAMENTAL** to our industry

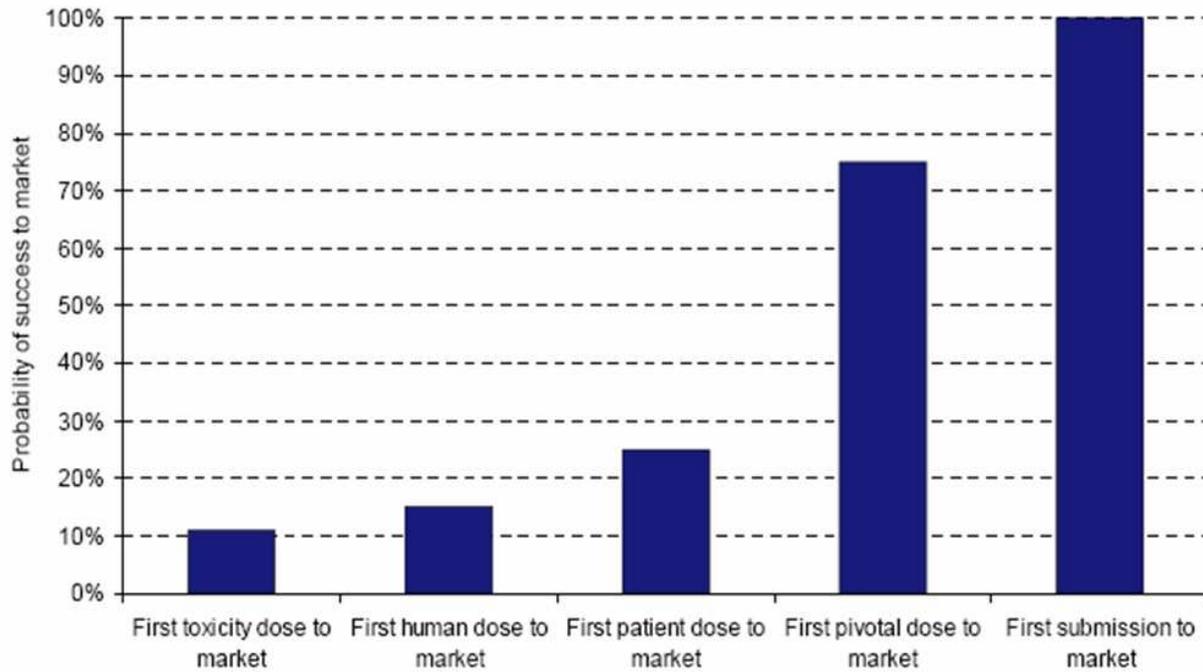


The drug development process





Probability of succes of reaching market (all drugs)



Probabilities of success to market were calculated using success rates between phase for ASs entering phase between 2001 and 2003 and year of assessment 2006.



High Quality and Efficient IP systems are essential for our industry

- Lundbeck's mission is to improve the quality of life for those suffering from psychiatric and neurological disorders such as depression and Alzheimer's disease

- We do that by research and development of novel and improved drugs

- Market exclusivity is absolutely key to
 - Enable return of investment
 - Financing tomorrow's medicines

- To contribute to innovation



Lundbecks most critical IPs

- Patent
- Patent term extension (SPC)
- Regulatory Data Protection (Data Exclusivity)
- Paediatric Exclusivity
- Orphan Drug Exclusivity
- Trademarks



Regulatory Data Protection

- RDP ensures that the data constituting the basis of a marketing approval of a new drug cannot be referred to by a generic company through out the duration of the Regulatory Data Protection Period (10 years in EU)

- RDP is essential for the innovative pharmaceutical industry

Lundbeck's experience on pan-European IP litigation



- Lundbeck's blockbuster drug Cipralex® is subject of significant litigation through-out Europe
- Cipralex® is protected by national patents and SPCs covering the active substance escitalopram or a process of its production
- Cipralex® is also subject of regulatory data protection
- Cipralex® is a registered trademark
- Lundbeck is or has been defending its IP rights against generic competitors throughout Europe, including in Austria, Belgium, Denmark, Finland, France, Germany, Holland, Hungary, Norway, Portugal, Romania, Spain and the UK



Lundbeck's learnings

→ Huge differences between European Countries in

- Patent knowledge and expertise of judges
- The conduct of the litigation procedure
 - Written vs oral procedure
 - Taking of evidence (saisie, discovery)
 - Use of technical experts
 - Cross-examination
 - The hearing (duration, conduct, etc)
 - Speed

→ Differences also seen in the national authorities view on Regulatory Data Protection



Learnings from other litigations

- National Courts may come to other conclusions on patentability than the EPO
 - Numerous examples of difference in evaluation of inventive step between the EPO and the UK Patent Court

- Huge variations in SPC interpretation between the European countries



Legal Certainty

- Legal certainty on IP rights are essential to our business
- Patents
 - SPCs
 - Regulatory Data Protection



Lundbeck's wish list for increased IP legal certainty in the EU

- A. A high quality and efficient patent grant system
- B. A high quality and efficient unified European patent and patent litigation system
- C. Further clarity and consistent national implementation on Regulatory Data Protection, SPC, and Paediatric Extensions
- D. A notification system (early resolution mechanism)
- E. Longer term: further development of the IP systems to provide sufficient incentive for the continued development of improved drugs



Lundbeck's wish list

A A high quality and efficient patent grant system

→ Quality and Efficiency in relation to EP Patents

- Consistency in assessment of patentability to provide legal certainty for patent owner and third parties
- Adjustment of EPO procedures so as not only to focus on faster grant procedure
 - We would wellcome a possibility of deferred examination be introduced
- Transparency in EPOs handling of specific cases, e.g. as to procedure when PACE has been requested



Lundbeck's wish list

B A high quality, cost-efficient unified European patent and patent litigation system

- Lundbeck wellcomes a high-quality efficient unified patent and patent court system
- Such system would considerably increase efficiency in the European IP space, but also significantly increase vulnerability
- The business impact is huge
- Quality is of outmost importance and far more important than costs
 - Only a high high quality system will lead to increased legal certainty
 - Only a high high quality system will be attractive to our industry

Lundbeck's wish list



B A high quality, cost-efficient unified European patent and patent litigation system

The Unified European Patent

- Lundbeck supports the creation of a unitary European patent based on the EP Patent system provided a satisfactory solution is provided on jurisdiction for such patents
- We agree on an overall level to the current proposal
- However, the current proposal has provisions on infringement and defense that would seem better included in an agreement relating to a European patent court system

Lundbeck's wish list



B A high quality, cost-efficient unified European patent and patent litigation system

A unified European Patent Court

- Lundbeck supports the creation of a unified European Patent Court system, but not for any prize
- Quality of court (both as to structure, jurisdiction, and procedure) is critically important
- Essential requirements are
 - High quality judges and procedure
 - Consistency irrespective of which division of the court is handling the matter
 - Resolution of national differences in questions on infringement, validity, etc
- The system needs to provide reasonable speed and effective preliminary measures



Lundbeck's wish list

B A high quality, cost-efficient unified European patent and patent litigation system

Quality

- Judges need to have the necessary knowledge and experience of patent law
- The procedure needs to be defined so as to ensure on the one hand uniformity on the other hand flexibility to optimize process for best possible elucidation of the particular case
 - One size does NOT fit all
 - Technical aspects may be the most essential in some cases, whereas legal aspects essential in other cases
 - System should allow for appropriate elucidation of critical aspects, irrespective of their nature
 - This applies to both written and oral procedure, inclusive cross-examinations
- We strongly support that validity and infringement cases be heard before the same division (previous proposal included bifurcation)



Lundbeck's wish list

B A high quality, cost-efficient unified European patent and patent litigation system

Consistency

- Huge differences in current national system, e.g. as to
 - pre-trial orders like saisie
 - Preliminary injunctions
 - Discovery
 - Expert witnesses
 - Cross-examination

- In the currently envisaged system with central and regional/national divisions it is critically important that all divisions deal with such issues in the same way

- If not there is a risk of forum shopping



Lundbeck's wish list

C a notification system

- Today, no system is in place for Lundbeck to be notified on generics that seek regulatory approval for a generic drug based on Lundbeck's data
- The health authorities do not consider possible patent infringement when granting marketing approvals on generic drugs
- Therefore, in many cases action can only be taken when the generic is close to or has entered the market
- If generic has entered the market, but later is asked to withdraw based on patent infringement, patients, pharmacies, doctors and regulatory authorities are impacted and the harm suffered by Lundbeck is irreparable

Lundbeck's wish list



C a notification system

- Lundbeck strongly supports the introduction of a notification system that would enable innovator companies to take action to resolve disputes before generic launch
- Such a system would considerably improve the legal certainty for all parties involved and provide a possibility of resolving IP infringement matters at an early stage
- Numerous litigations and distortion of the market could thereby be avoided
- A notification system is already in existence for parallel imported drugs



Lundbeck's wish list

D improved legal certainty on Regulatory Data Exclusivity

- Regulatory Data Exclusivity is a right which is in the exclusive control of the regulatory authorities
- Inconsistency in how this is applied between European Countries
- We would welcome increased legal certainty and consistency to add to the legal clarity for not only the innovator company, but also third parties



Lundbeck's wish list

D improved legal certainty on SPC and paediatric exclusivities

- SPC and Paediatric Exclusivity are very important IPs for the innovative pharmaceutical industry and have huge business impact
- National differences in interpretation of SPC and Paediatric Exclusivity regulations exist
- This gives rise to uncertainty and inconsistency across Europe
- Lundbeck would welcome adjustment of these regulations to improve clarity, consistency and thereby legal certainty for all parties involved



Lundbeck's wish list

E longer term

- Further development of the exclusivity available to ensure sufficient incentive for the innovative drug industry to make the huge investment needed in order to bring improved drugs and treatments on the market to the benefit of patients, their families, the society, etc



Conclusion

- Lundbeck's business – as that of any other innovative pharmaceutical company – is highly dependent on a high-quality and efficient IP system
- A high-quality IP system is an essential incentive and requirement for the development of improved drugs to the benefit of patients, their relatives and society
- Legal certainty is of outmost importance
- Quality should take the highest priority when creating new or modifying existing IP systems



THANK YOU