



The Brachyspina Genetic Test

The story of 6 license agreements in 6 months



Niels Lysholm Engelhard
Senior Commercial Officer



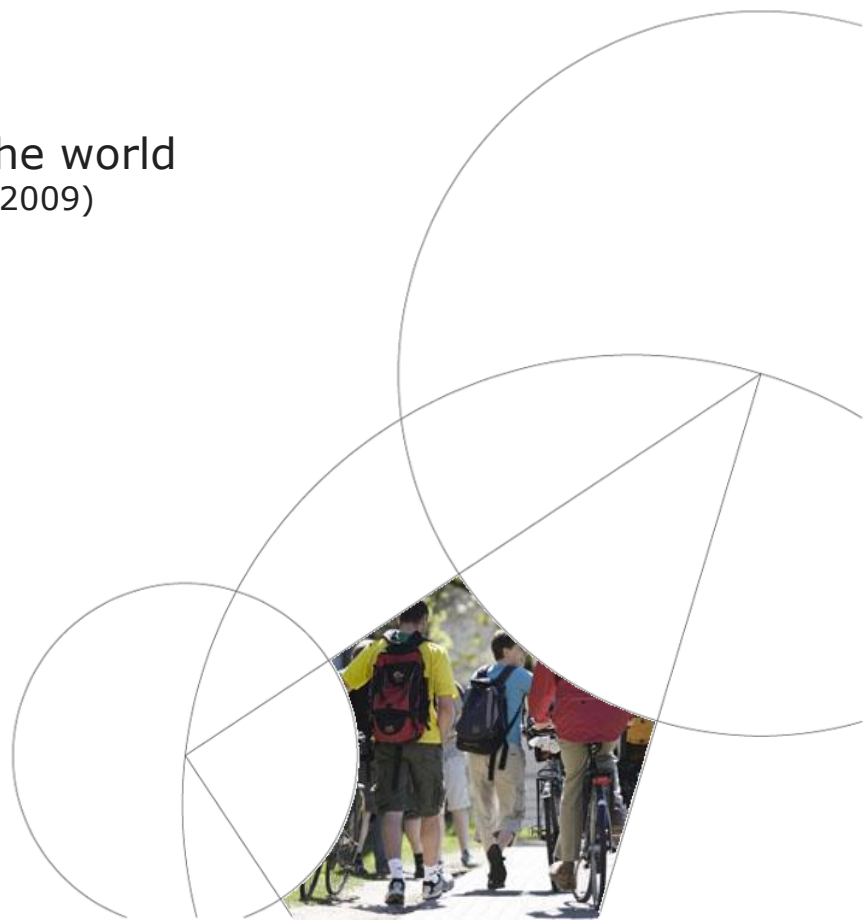
Outline

- Introduction to the University of Copenhagen
- How it all began
- The invention(s)
- First license agreement
- Next 6 license agreements
- EU competition law
- Lessons learned
- Questions



The largest university in Scandinavia

- 37,000 students
- 7,500 employees, including 5,000 scientists
- 8 Nobel prizes
- € 800 million turnover
- Ranked:
 - no. 8 in Europe og no. 43 in the world
(Academic Ranking of World Universities, 2009)
 - no. 51 in the world
(Times Higher, 2009)



The Tech Transfer Office

Staff

- Head of Tech Transfer Office
- 3 Commercial Officers
- 4 legal Officers



Results: University of Copenhagen input/output 2007 - 2011

Results 2007-2011	2007	2008	2009	2010	2011
No. of inventions disclosures	72	74	45	40	58
No of inventions where University has assumed rights	28	28	15	17	17
No of patents applied for	13	21	17	11	11
No of licensing agreements	9	19	13	12	21
No of spin-outs	1	3	0	0	0
No of licensing agreements in portfolio (2007-2010)	37	43	50	58	79
Licensing agreements in portfolio generating income to the University	14	15	27	15	18



How it all began

2006 Brachyspina syndrome described
Professor Jørgen Steen Agerholm et al

2007 Genetic background elucidated

- The lethal condition occurs in one-quarter of the matings
- The US bull Sweet-Haven Tradition
- Recessives





© J.S. Agerholm, University of Copenhagen, Denmark

10 cm

Courtesy of Prof. Jørgen Steen Agerholm



What is the value of the invention?

Example – Canada

- Frequency of Brachyspina in population approx. 4,4%
- 76% of current population connected to Sweat Haven Tradition
- 1 of 750 pregnancies results in early embryonic death
- 1 of 100 matings result in embryonic death

Source: Bethany Muir, Holstein Canada May 2011



Genetic code for the Brachyspina Syndrome

2007-2008



University of Copenhagen

- Department of Large Animal Sciences
- Department of Basic Animal and Veterinary Sciences
- GIGA Institute
- Unit of Animal Genetics

2008

Invention disclosure filed- August





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(71) Applicants:

- **Université de Liège**
4031 Angleur (BE)
- **University of Copenhagen**
1017 Copenhagen K (DK)

(72) Inventors:

- **Georges, Michel**
4161 Villers-aux-Tours (BE)

- **Wouter, Coppieters**
3401 Landen (BE)
- **Charlier, Carole**
4140 Sprimont (BE)
- **Agerholm, Jørgen Steen**
2650 Hvidovre (DK)
- **Fredholm, Merete**
2800 Lyngby (DK)

(74) Representative: **Vossius & Partner**
Siebertstraße 4
81675 München (DE)

(54) **A genetic marker test for brachyspina and fertility in cattle**

(57) This invention relates to methods for the detection of bovine that are affected by or carriers of Brachyspina (BS). The present invention provides a method for determining whether a bovine is affected by or carrier of

BS by analyzing its genomic DNA or its RNA. The method can be used to perform marker assisted selection or genomic selection for increased fertility in said bovine.

A genetic test marker for brachyspina and fertility in cattle

2008-2009

- Joint ownership agreement
 - University of Liege responsible for patent prosecution
 - University of Copenhagen responsible for commercialisation
- Indirect test
- Approx. 95% accuracy
- No dead calves reported in North America



Licensing strategy

Non-exclusive versus Exclusive

- | | |
|---------------------------------------|--|
| (+) Maximizes commercial output | (+) Financial incentive for Licensee |
| (+) Reduces the commercial risk | (+) Dealing with only one Licensee |
| (+) May suit industry practice | (+) Patent cost covered |
| (+) Greater market penetration | (+) Policing of IPR |
| (-) Difficult to find licensees | (-) "All eggs in one basket" |
| (-) Difficult to finance patent costs | (-) Risk of weak penetration in some markets |
| (-) Administrative burden | (-) May limit the total commercial output |



Commercialisation

2009-2010

First License agreement

Non-exclusive – limited territory

Patent costs

- Maintenance fee – national phase
- New maintenance fee after national phase divided between Licensees
- Patents cost to be divided among licensees if new licensee got on board before national phase

(+) "Fair" distribution of patent costs

(-) When to divide which share



Mutation Identified

2010-2011

- Mutation identified
- March 25 2011 US Holstein Association Declares Brachyspina an undesirable recessive trait
- May 2011 Priority patent application filed on "mutation Test"
- Request for licenses pouring in



Revised Fee Structure in License Agreements

- Royalty structure
 - Percentage of Net Sales
 - Minimum fixed fee per test
- Single gene test
- Multiple Biomarkers tested
 - e.g. Illuminia genotyping chip



The Dream of a Tech Transfer Office

6 License agreements
from
June to November 2011



....Copenhagen, we may
have a problem....

March 2012

...In our licenses, we need to cancel the minimum price
(=minimum royalty fee for the test X euros) otherwise, our
licenses are void ..

.....**EU Competition Law**.....



MEMORANDUM

ON LICENSING OF THE BRACHYSPINA TEST PROCEDURE TECHNOLOGY

Conclusion

“Application of a minimum royalty does not contravene EU competition law in so far as the aim of applying a minimum royalty fee is neither an attempt to fix the resale price of a licensee's product nor to restrict the passive sale of the products.”...

External Legal Counsel: Plesner



Lessons learned

- "Practical" supercedes "fair" in structuring maintenance fees
- Combination of percentage and fixed fee for royalty payment may be useful fee structure in out-licensing of genetic test

Keep it simple!!





Thank you!



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