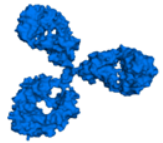


# ***Novel transgenic technology for antibody production***

***Dr. Imre Kacskovics, CEO  
ImmunoGenes***

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kacskovics@immunogenes.com  
www.immunogenes.com



# Opportunity in the Big Three of Antibody Production

## *Therapeutics – Diagnostics – Research Reagents*

### **Polyclonal market - 3.5 Billion (€)**

#### **Growing demand**

- 15% annual growth rate - therapy
- 6-7 % annual growth rate - diagnostic and in vitro/research

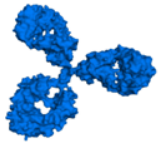
#### **Indicators for trend for humanized polyclonals produced in animals**

- Hematech (cattle) – Acquired in 2005 by Kirin for 31 Million (€)
- THP (rabbit) – Acquired in 2007 by Roche for 40 Million (€)
- Revivicor (pig) – In developmental phase

### **Monoclonal market - 12.5-14 Billion (€)**

#### **Explosive growth in all of the Big Three**

- 18 commercial products for human therapy currently on the market
- 170 - 200 in the R&D pipeline

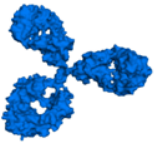


## History

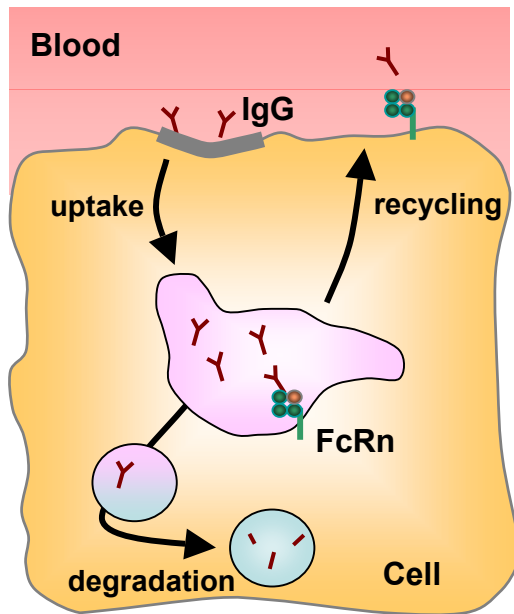
- 1995 - initial idea: secreting more IgG into cows' milk (against human intestinal pathogens)
- 2002 - study of the regulation of the bovine neonatal Fc receptor (FcRn)

## ***ImmunoGenes*** idea and proposition

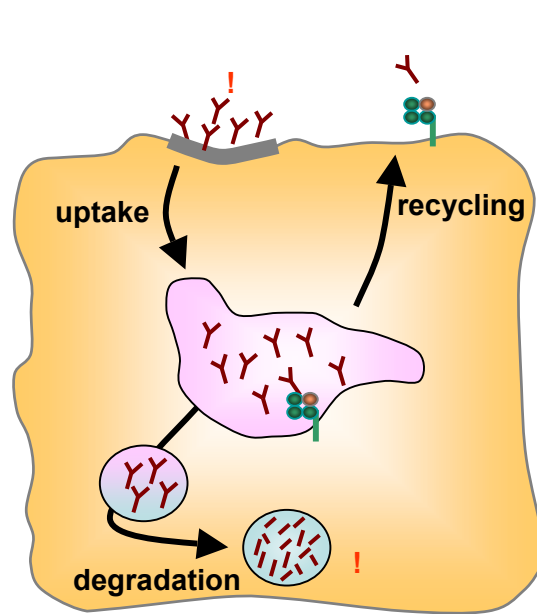
- 2006 - superimmunization and increased efficacy of antigen specific antibodies by creating FcRn transgenic animals



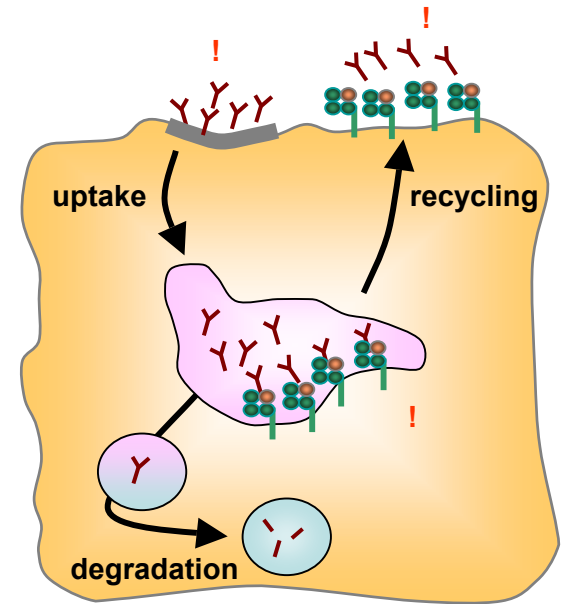
# Technology: antibody (IgG) is protected from fast degradation in cells



**BASIC SITUATION**  
 Few IgG - efficient protection:  
 IgG is back to serum



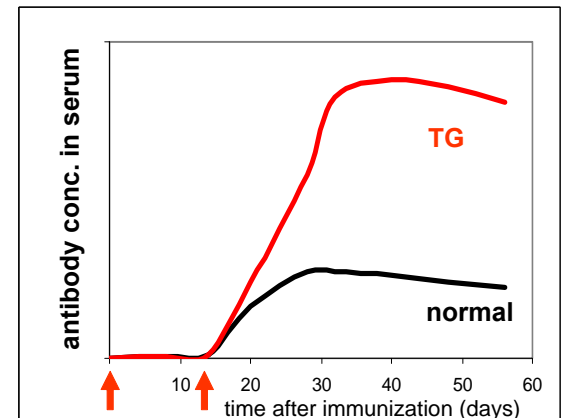
**NORMAL ANIMAL IMMUNIZATION**  
 More IgG - poor protection:  
 many IgGs are *degraded* in cells

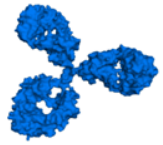


**TRANSGENIC ANIMAL IMMUNIZATION**  
 More IgG - *excellent* protection:  
 many more IgGs are back to serum

## FcRn *over*expression

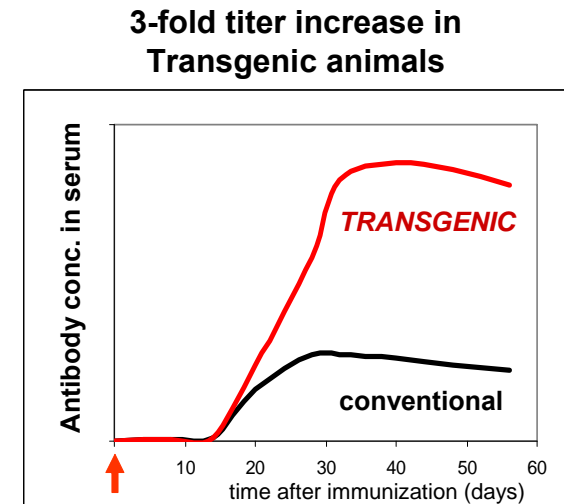
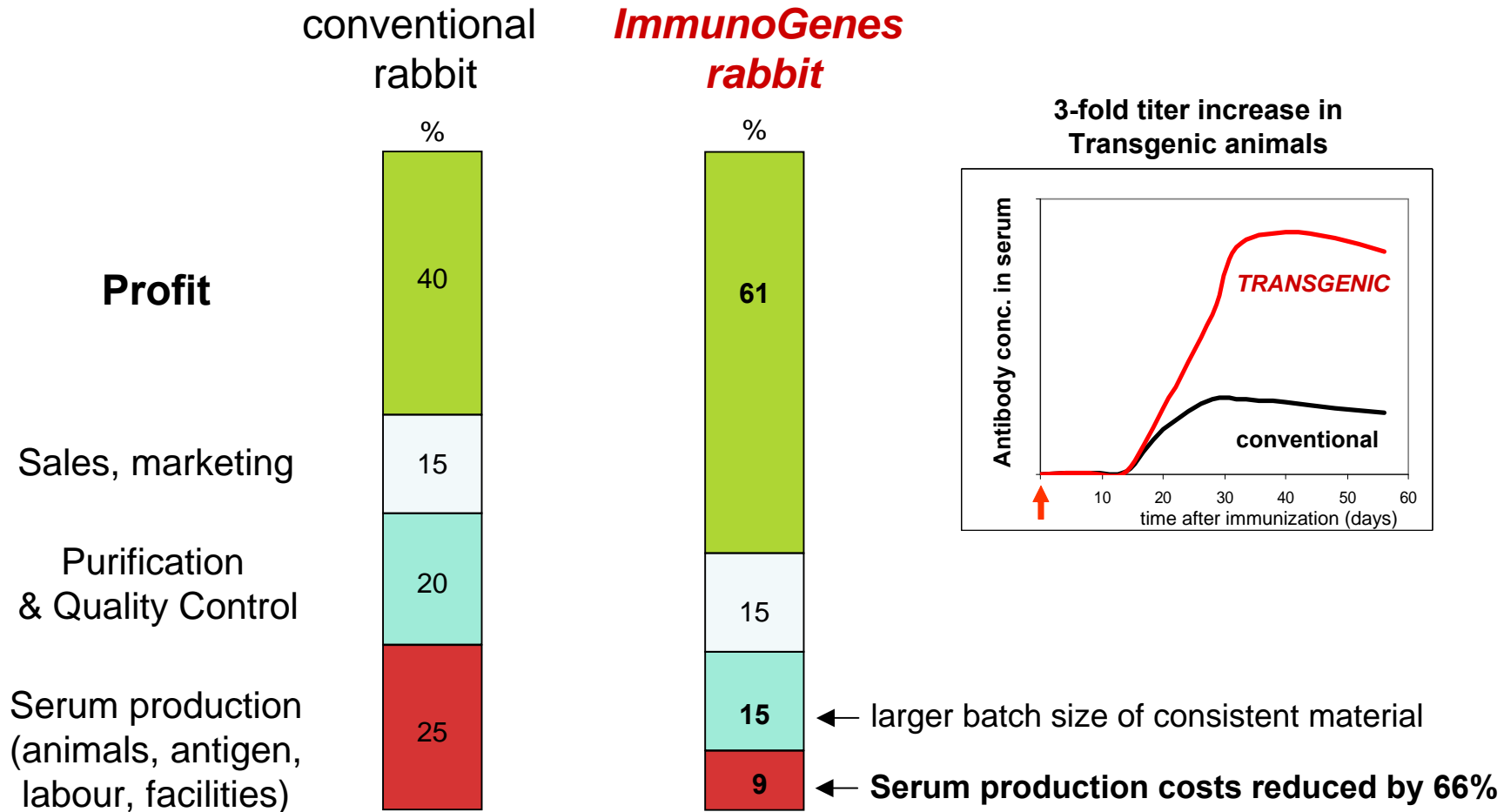
- more antibody (IgG) is protected from degradation
- increased IgG in serum
- **more antibody – sooner - for less**



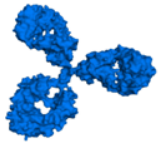


# Increase Profit with **ImmunoGenes** Technology

*ImmunoGenes Technology provides the opportunity to increase profits by **50%** on polyclonal antibodies produced for therapy, diagnosis or research*

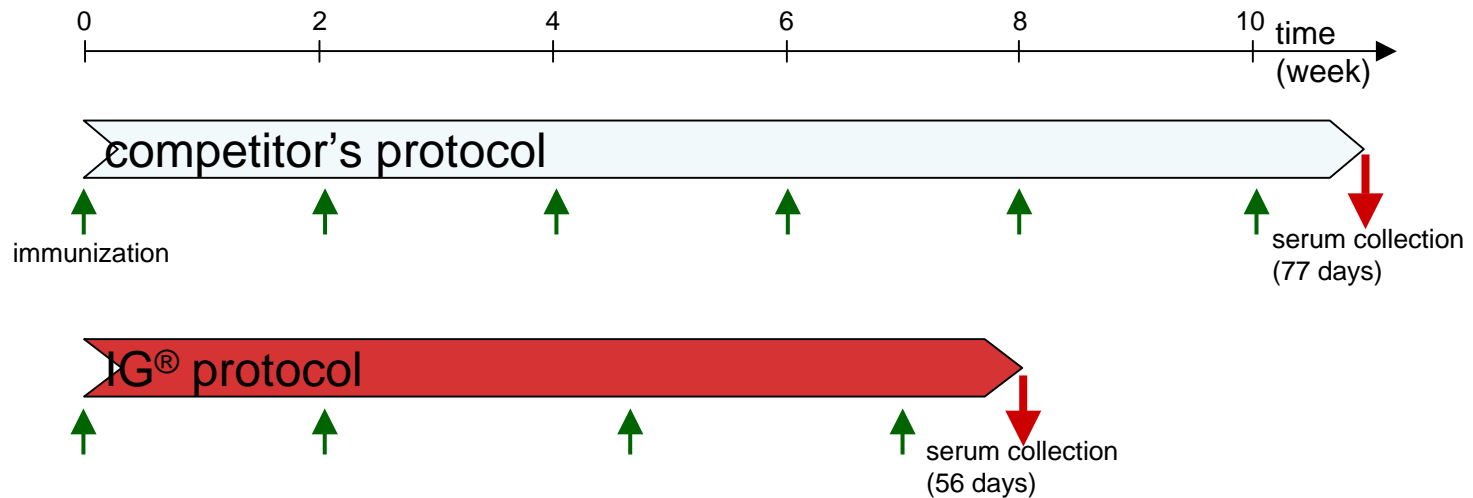


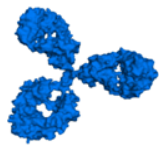
+ competitive edge: improved time efficiency (appr. 30% reduction)



## Competitive edge using *ImmunoGenes* technology in polyclonal antibody production

**SOONER:** time-to-market for a new product and related earlier sales per month, custom made antibodies – *appr. 30% time reduction (important in e.g. epidemics and bio-defense)*





# *From this time forth*, key players in polyclonal segments are using sub-optimal methods in a highly competitive market

## Approaches

- animals after hyperimmunization
- R&D in human polyclonals
  - Hematech/Kirin – human polyclonals in cattle (2005; 31 Million (€))
  - THP/Roche - human polyclonals in rabbit (2007; 40 Million (€))
  - Revivicor - human polyclonals in pig

## Competitors

- harvesting in humans after exposure / immunization
- R&D in human polyclonals
  - Symphogen– recombinant technology for human polyclonals

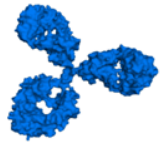
## Key players

### ***Diagnostics***

Abbot  
 Biotest  
 BMS  
 J+J  
 Lilly  
 Roche  
 Sigma  
 Schering Plough  
 Santa Cruz

### ***Therapeutics***

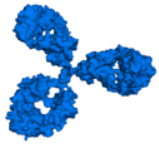
Fresenius  
 Genzyme  
 GSK  
 Nabi  
 Nycomed  
 Pfizer  
 Protherics  
 Wellcome  
 TaleCris



# Why IP and technology evaluation are important?

1. It is critical to decide from the inventors' point of view whether it is worth investing time, effort and finances into continuing technology transfer.
2. In cases such as this where inventors developed the technology under institutional framework the technology is considered as a service invention. Therefore, institutions are highly interested whether inventions represent real economical advantages.
3. It is critical for achieving an appropriate license agreement between Institutions and spin-off company founded by inventors.
4. It is critical to attract investors.
5. It is critical to achieve an appropriate share for the inventors in the spin-off company after seed investment and capital increase.





# First steps...

## Intellectual property:

Nov 2006 - 1st patent application (Danubia Patent and Law Office)

July 2007 – 2nd patent application (Danubia)

Nov 2007 – PCT from 1st and 2nd applications (Danubia)

*IP owners: Eötvös Loránd University, Budapest, Hungary (ELTE) and  
Agricultural Biotechnology Center, Gödöllő, Hungary (ABC)*

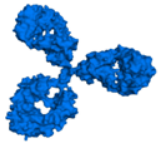
## Evaluation:

The IP position and economical advantages of this technology have been evaluated and recognized by analysts of the Hungarian Patent Office (within the Intellectual Property/ technology valuation pilot project; Jan 2007)

## Technology transfer:

Sept 2007 – ImmunoGenes Kft, Hungary was founded as a spin-off company of ELTE and ABC

Jan 2008 – License Agreement with ELTE and ABC



## IP position

PCT\*: FcRn over-expression increases production efficiency of immunoglobulins and enhances immune response in vivo (all mammals)

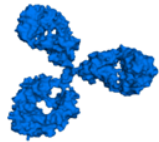
Rabbit is the preferred animal to produce polyclonal antibody production and the use of our technology in this species is fully protected by IP

Mouse and rabbit are the preferred animals for the production of monoclonal antibodies and use of our technology in these animals is fully protected by IP

We have additional patent strategies to secure IP on enhancing antibody quantity, quality and rate of production

Collaborations with internationally experienced patent law firms have been established

\*Patent Cooperation Treaty



# Company and network

## Management:

**Wolfgang Oster, Executive Chairman**, MD, PhD (USA)

serial entrepreneur and investor in US / Europe: Polytechnos Venture Fund II, Managing Partner; FiveLakes Venture Partners, General Partner; Member Board of Directors, including chairman, in several US and EU biotech companies; Business Angel and Advisor

**Imre Kacs Kovics, Vice Chairman and CEO**, DVM, PhD, Eötvös Loránd University (Hungary)  
expert in immunoglobulins and Fc receptors areas

**Zsuzsanna Bősze Chief Scientific Officer**, PhD, DSc, Agricultural Biotechnology Center (Hungary) expert in generating transgenic animals

**Christian Schneider, Chief Business Officer**, DVM, PhD, MBA (Germany)

extensive work and investment experience in the areas of diagnostics and medical R&D; serial entrepreneur and investor in US / Europe: Polytechnos Venture Fund II, Managing Partner; FiveLakes Venture Partners

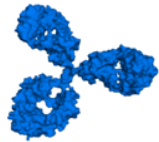
**Gabor-Paul Blechta, General Counsel**, PhD (Switzerland)

executive director, chief claim and risk officer in US / Europe: Winterthur International, UBS Financial Services-Zürich/London, Sulzer Medica/Centerpulze, IMI Intelligent Medical Implant

**Andreas Graf von Stosch, IP structure**, LL.M., PhD (Germany)

European patent attorney, Bosch – Graf von Stosch Jehle, Munich

**Kevin Dwyer, Regulatory affairs and manufacturing**, Managing Partner, VP, Business Development, Pacific BioDevelopment, LLC (USA)



# Company and network

## Scientific and business council:

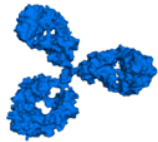
**Anna Erdei**, PhD, DSc – Chair Immunology, Eötvös Loránd University, Corr. Member of the Hungarian Academy of Sciences, Secretary General of the European Federation of Immunological Societies, Council member of the International Union of Immunological Societies (Hungary)

**John E. Butler**, PhD – Professor Immunology, University of Iowa, IA, Scientific Advisor – Revivicor (USA)

**Lennart Hammarström**, MD, PhD – Professor, Clinical Immunology, Karolinska Institute (Sweden)

**Richard A. Goldsby**, PhD – Professor of Biology, Amherst College, MA, Co-Founder – Hematech (USA)

**Bruce Whitelaw**, PhD - Head of Division of Developmental Biology, The Roslin Institute (UK)



# Investment Opportunity of ImmunoGenes

1. technology addresses a multibillion dollar and growing worldwide market with a need for increasing efficiencies
2. Manufacturing costs are traditionally very high, resulting in low profit margins
3. ImmunoGenes technology present a novel and patent protected improvement for the polyclonal antibody market
4. ImmunoGenes' technology has already been shown to work in mice and this experience is helpful to establish the concept in rabbits
5. time to market and financial resources to market are expected to be relatively short/limited
6. Hungary offers substantial advantages (cost efficiencies, central location, EU memberstate, easy access to management talent from EU, scientific networks with leading institutions in EU and US)
7. ImmunoGenes intends to make the location in Hungary a competitive advantage for the development of the company and expects increased foreign investor interest based on this geographic location
8. an international and experienced management team as well as an international scientific advisory board with reach and specific know how in ImmunoGenes' areas of interest
9. the business plan projects a profitable business in the year 2011