BIOTEC PHARMACON

Immunity for Life®

Forskningsdagene 2005

28.09.2005

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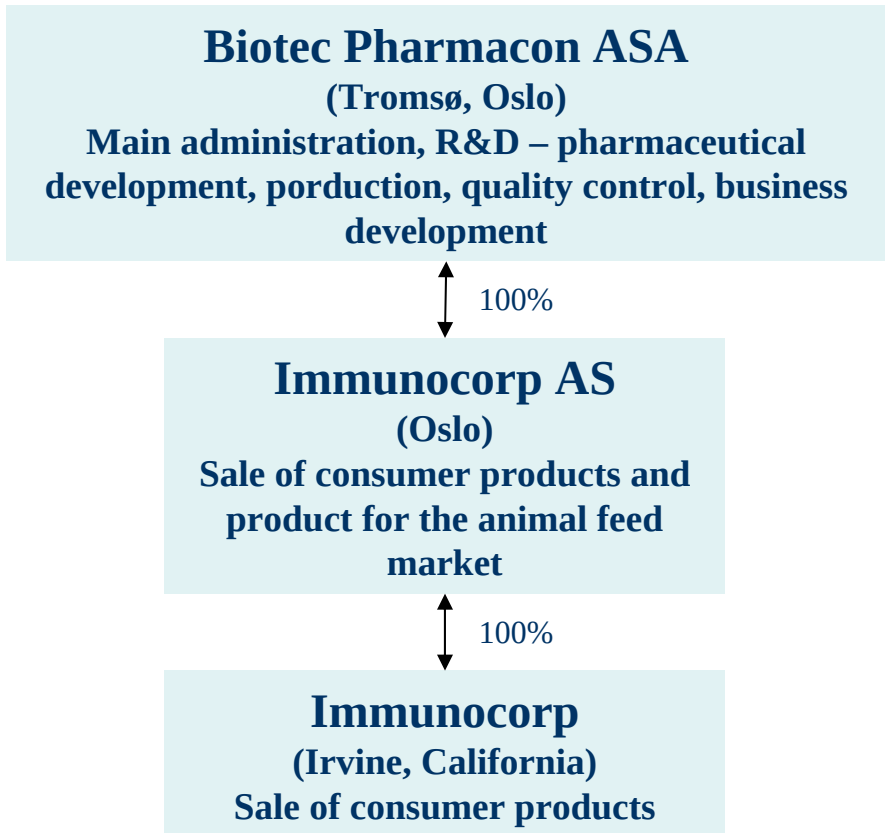
Agenda

- Presentation of Biotec Pharmacon ASA
- Definition of Intellectual Property (IP)
- How is Biotec Pharmacon dealing with IP ? – a practical approach defining core elements
- Case

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Biotec Pharmacon ASA

- A biopharmaceutical company with immunomodulating products for humans and animals, and marine enzymes for life science
- Started in 1990 based on work conducted at the University of Tromsø
- 55 employees in Tromsø, Oslo and Irvine (California)
- Has applied for listing at the Norwegian Stock Exchange with focus on finalizing this process in the end of October 2005.



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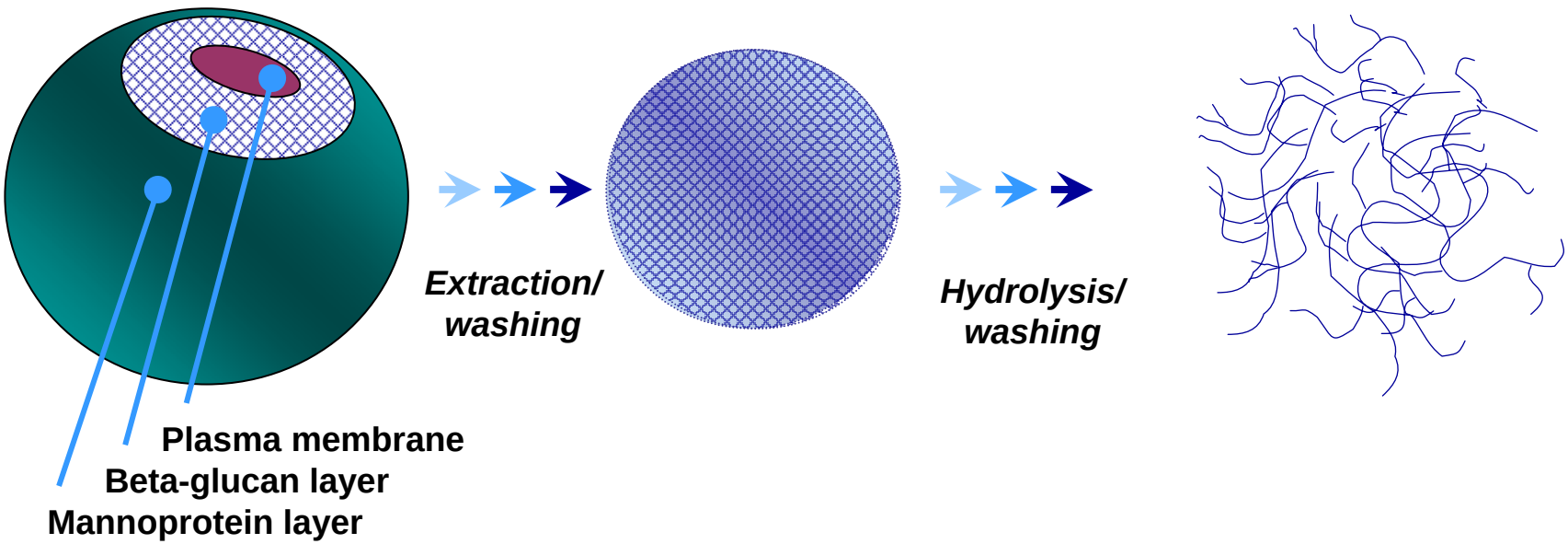
Biotec Pharmacon ASA

- Two major areas of interest (**pharmaceutical development** and **sale of non-pharmaceutical products developed in-house**)
- Main focus **- pharmaceutical development** – use of beta-glucans for treatment of cancer and wounds.
- **Non-pharmaceutical products**: Biochemicals, cosmetic articles, nutraceuticals as well as health and growth promoting products for animals.
- Marine bioprospecting is the companies source for new bioactive substances

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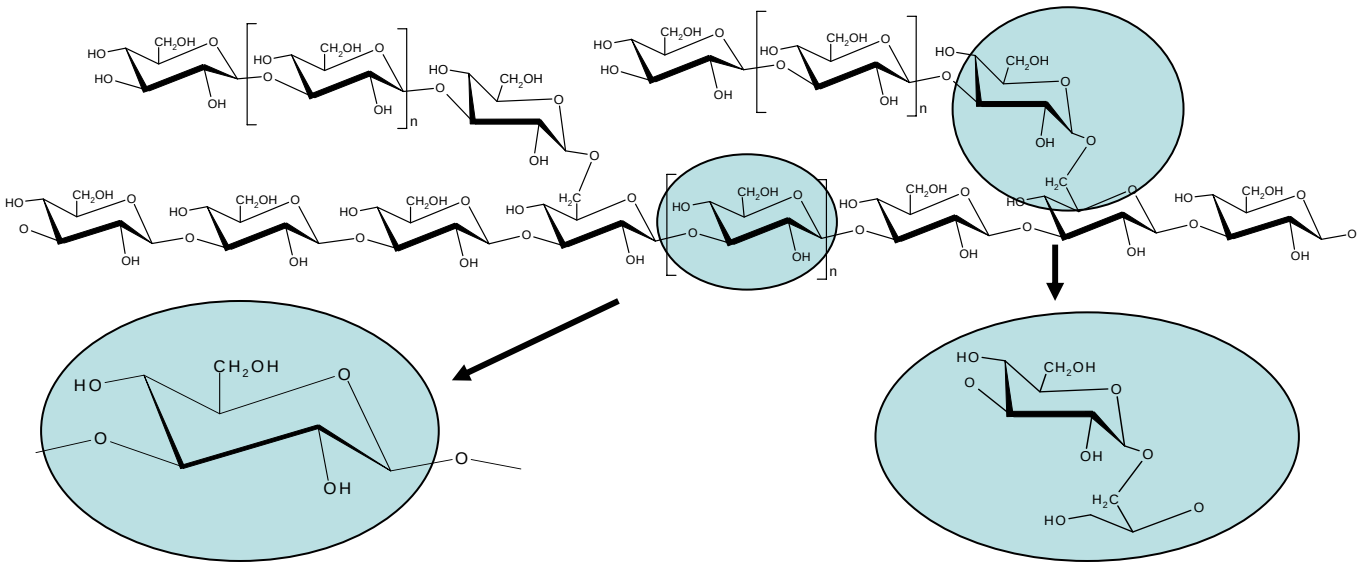
SBG – an activ immunomodulator (process)

Yeast cell wall **β-glucan particle** **(soluble) β-glucan**



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SBG - an activ immunomodulator (structure)

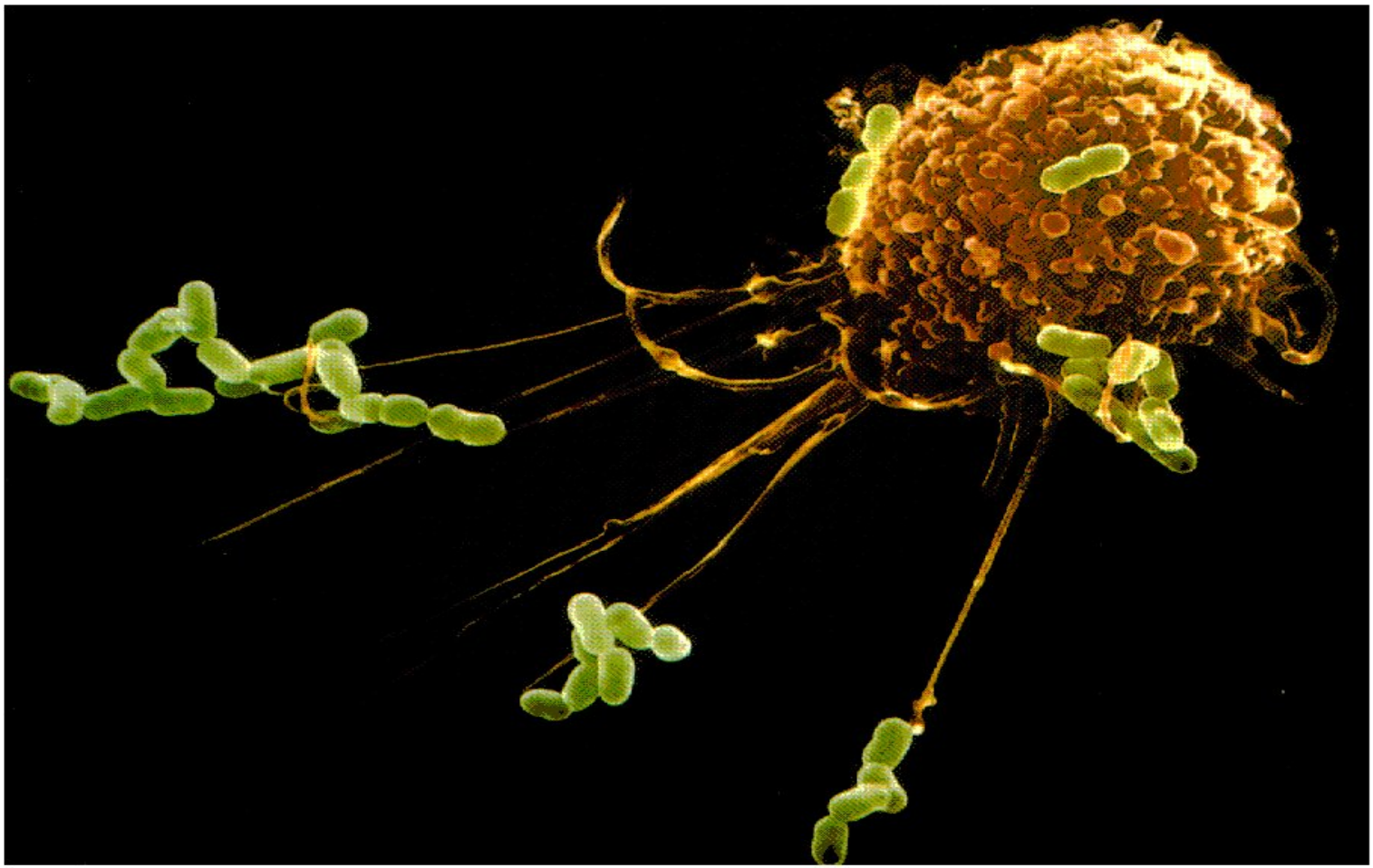


β-1,3-D-glucosyl

β-1,6-D-glucosyl

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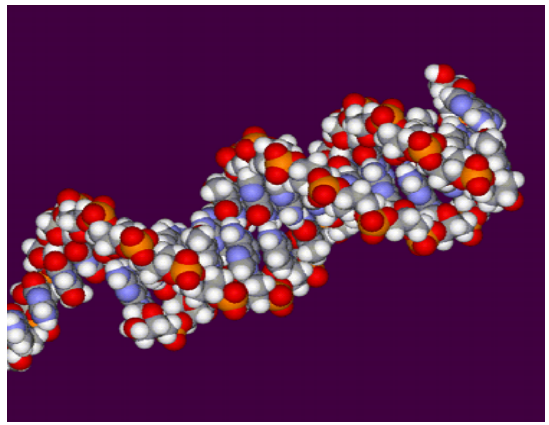
SBG - an activ immunomodulator (function)

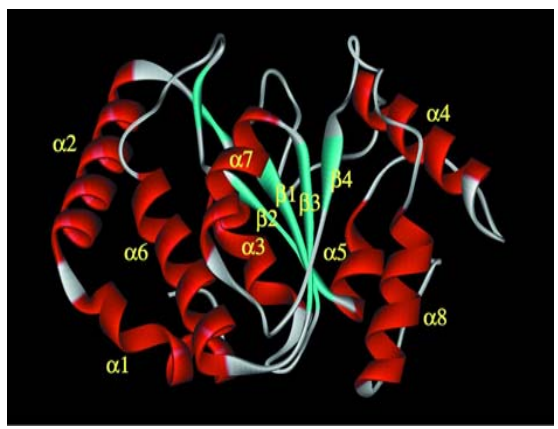


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Biochemicals

- **<u>Shrimp alkaline phoshatase</u> (SAP): gene cloning, PCR-clean up;**
- **<u>Uracil DNA-glycosylase</u> (UDG): removal of false positives before PCR analysis**
- **<u>DNA-ase (ds-DNA-ase):</u> removes PCR-contaminations**
- **<u>Chlamysin:</u> antibacterial protein; replacement of antibiotics**





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Consumer products

- Cosmetics (Immuderm®; nbg®24:7™)
- Nutraceuticals (Immutol®; nbg®24:7™)



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Animal health products

- The main product is MacroGard® Feed Ingredient
- Beta-glucan products
- Aquaculture and livestock market

MACROGARD®



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Intellectual Property (IP) – a short definition ?

- Intellectual Property (IP) is a defined by WIPO as the combination of:

a. Industrial Property including patentable inventions, trademarks, designs and geographic indications of source (Champagne); and

b. Copyright protecting literary and artistic works – being used in commerce.

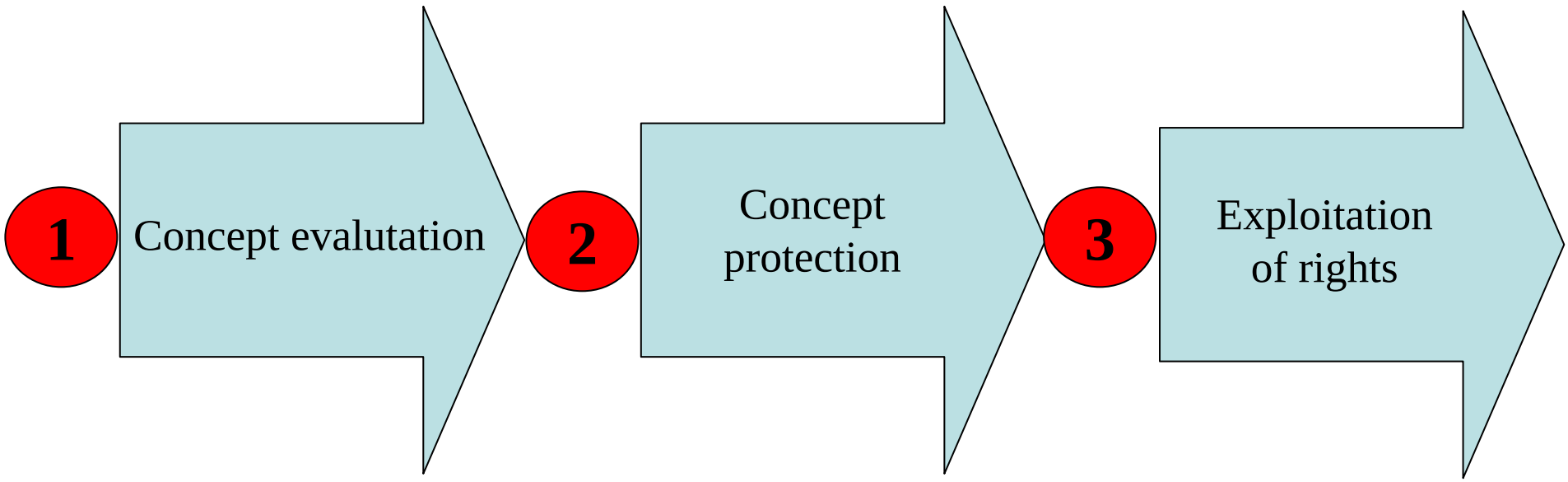
What about domain names, trade secrets, contracts, guidelines, … ?

- Intellectual Property Rights (IPR) are the legal rights derived from this IP

- More information on: http://www.wipo.int/about-ip/en/ and http://www.tu.no/bedriftshjelperen/

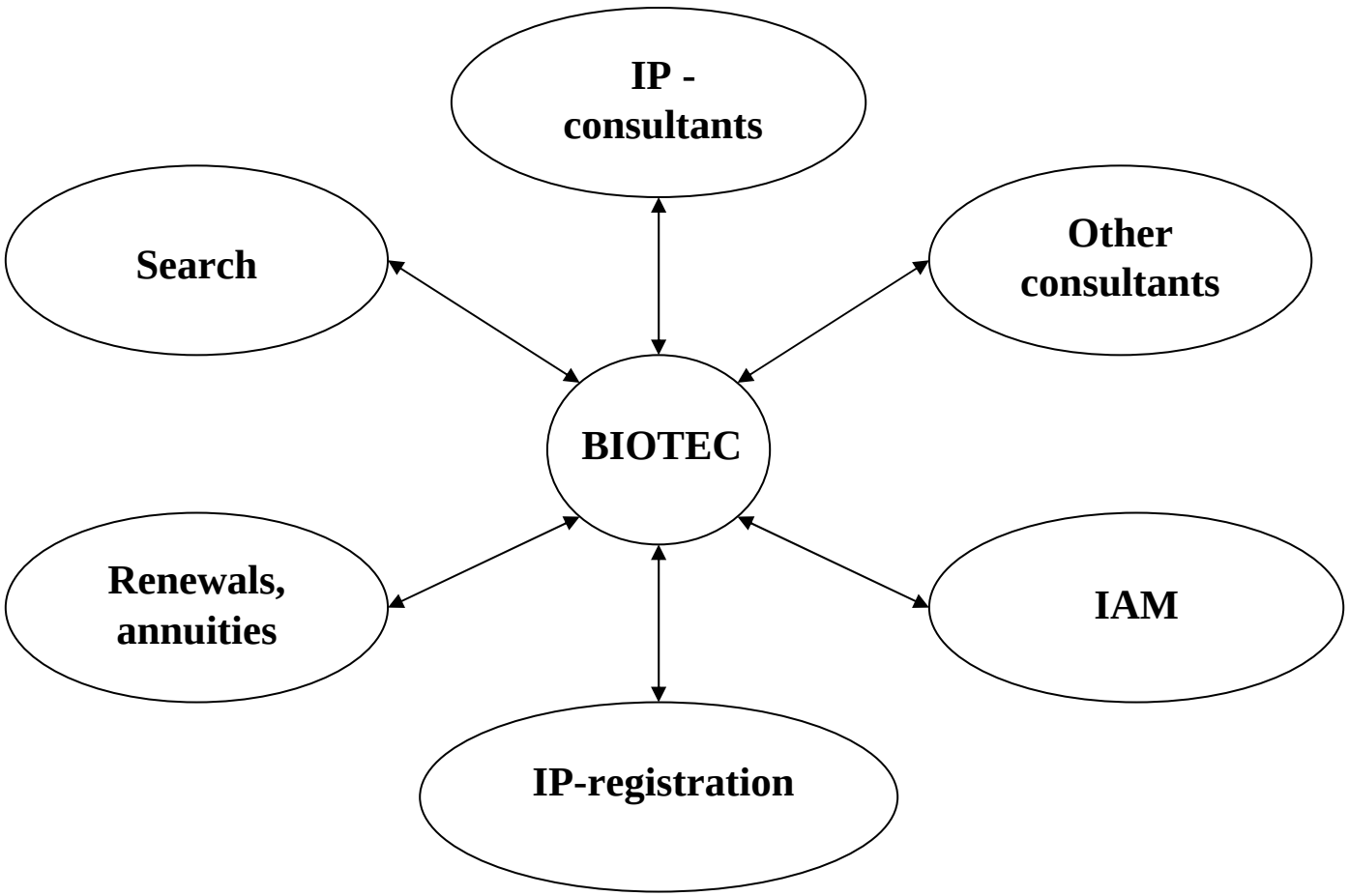
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Biotec Pharmacons approach to administrate IP



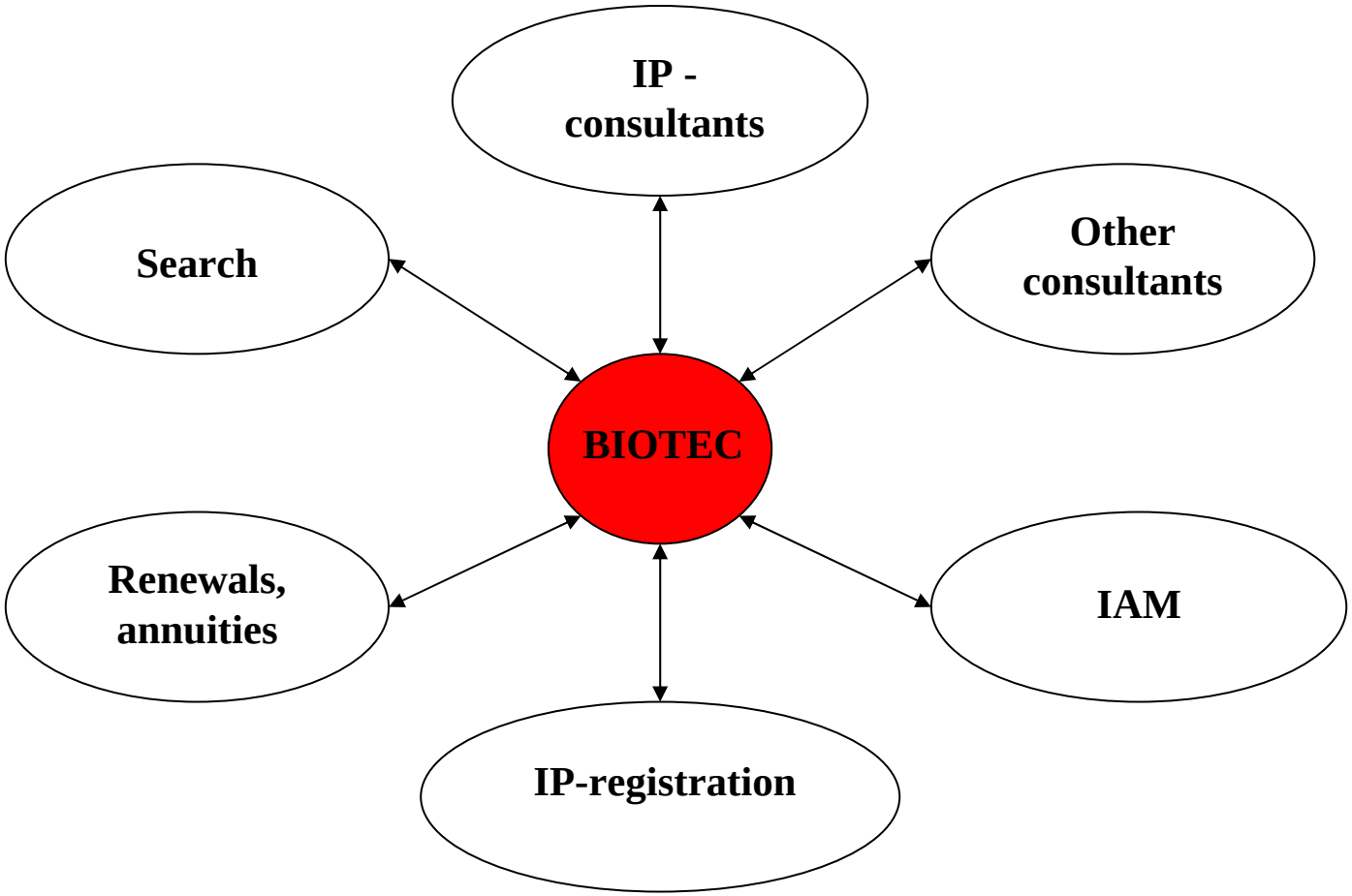
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Biotec Pharmacons approach –partners, tools and activities



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Biotec Pharmacons approach –partners, tools and activities



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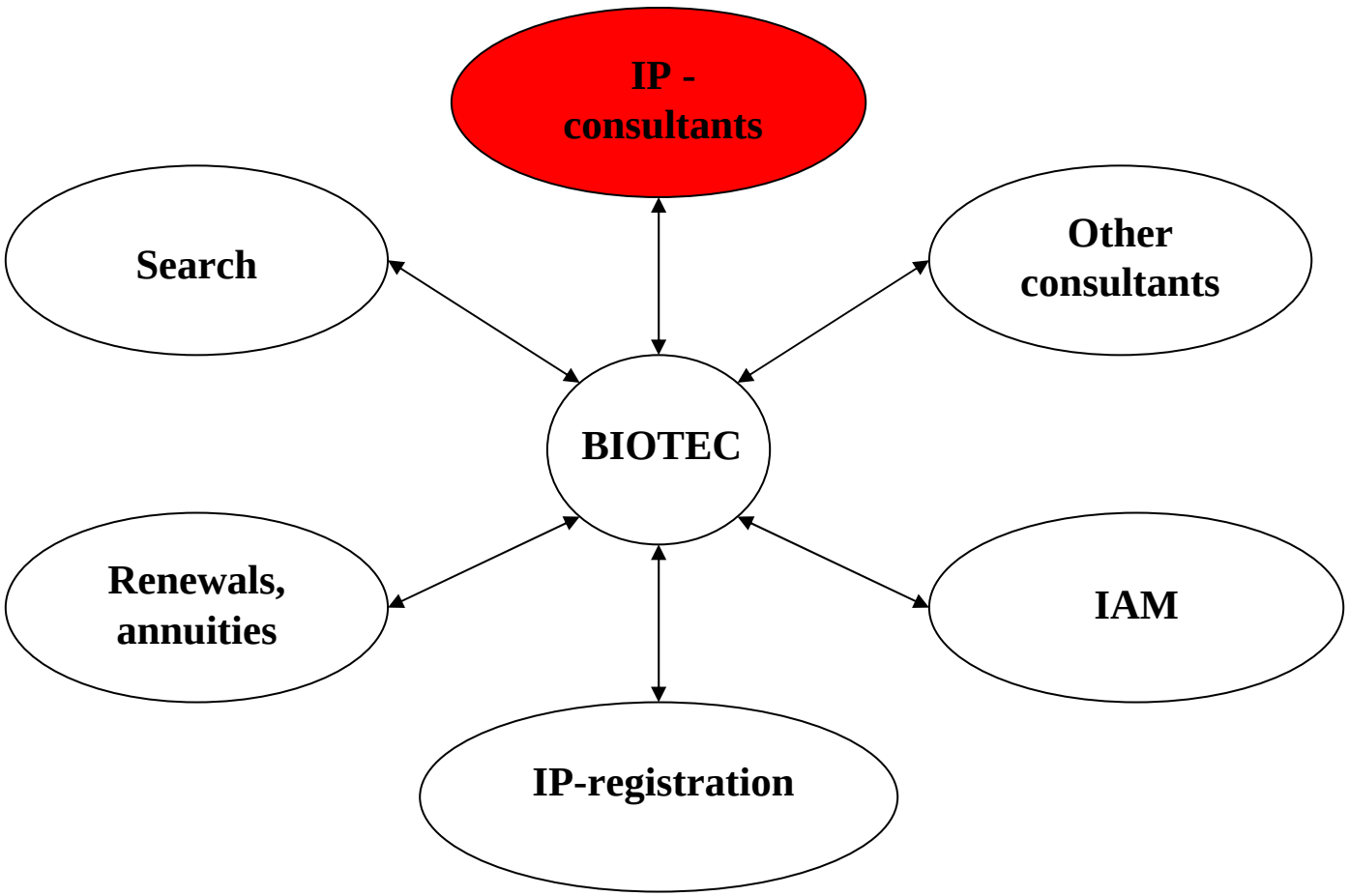
Biotec Pharmacons internal IP-activities

Examples:

- Administration of the network
- Idea/concept development – focus on product- and IP-portfolio
- Evalutation of new ideas / inventions
- Freedom-to-operate analysis
- Commercialization activities (out- in licensing, valuation of rights, identifying and creating possibilities)
- Education
- Administration of infringement cases and law suits
- Administration of the IP-portfolio (protection, registration, auditing)
- Internal (employee contracts) and external contracts (MTA, SA, DA, LA) and organizational activities like guidelines, IDS, laboratory notebooks and so forth

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Biotec Pharmacons approach –partners, tools and activities



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IP-consultants

Central in our strategy

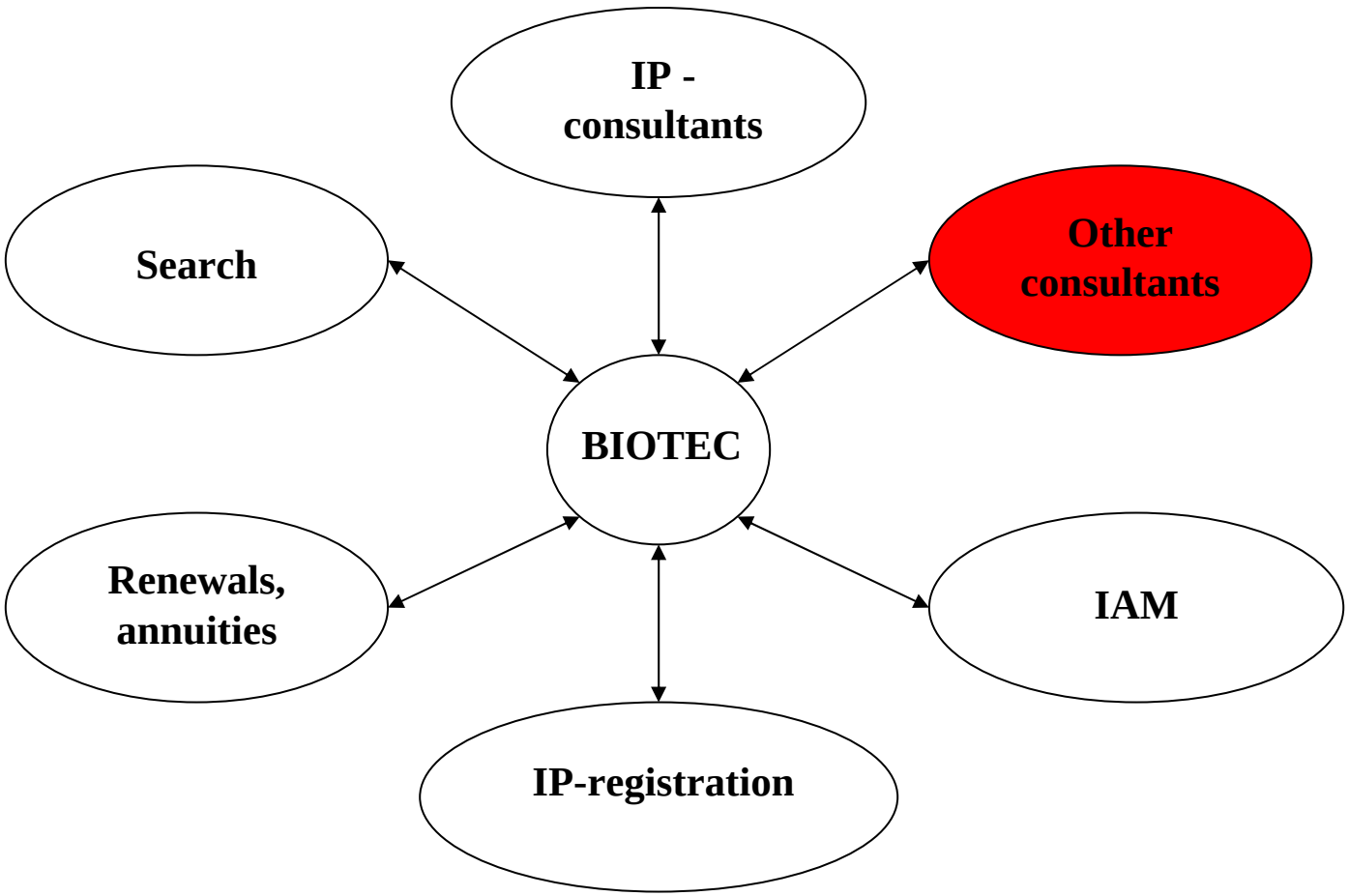
- **Choice 1:** In-house administration / IP-agent (cases abroad, own capacity and competence) ?
- **Choice 2:** IP-agent: In Norway or abroad (competence, capacity, service level, price, …) ?
- **Choice 3:** "In-house" contra "case-focused" (business strategy, trade secrets, …) ?

Central tasks:

- Registration of rights (the whole process from idea generation to opposition)
- IP-strategies
- Infringement cases
- Quality control (IP-portfolio)

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Biotec Pharmacons approach –partners, tools and activities



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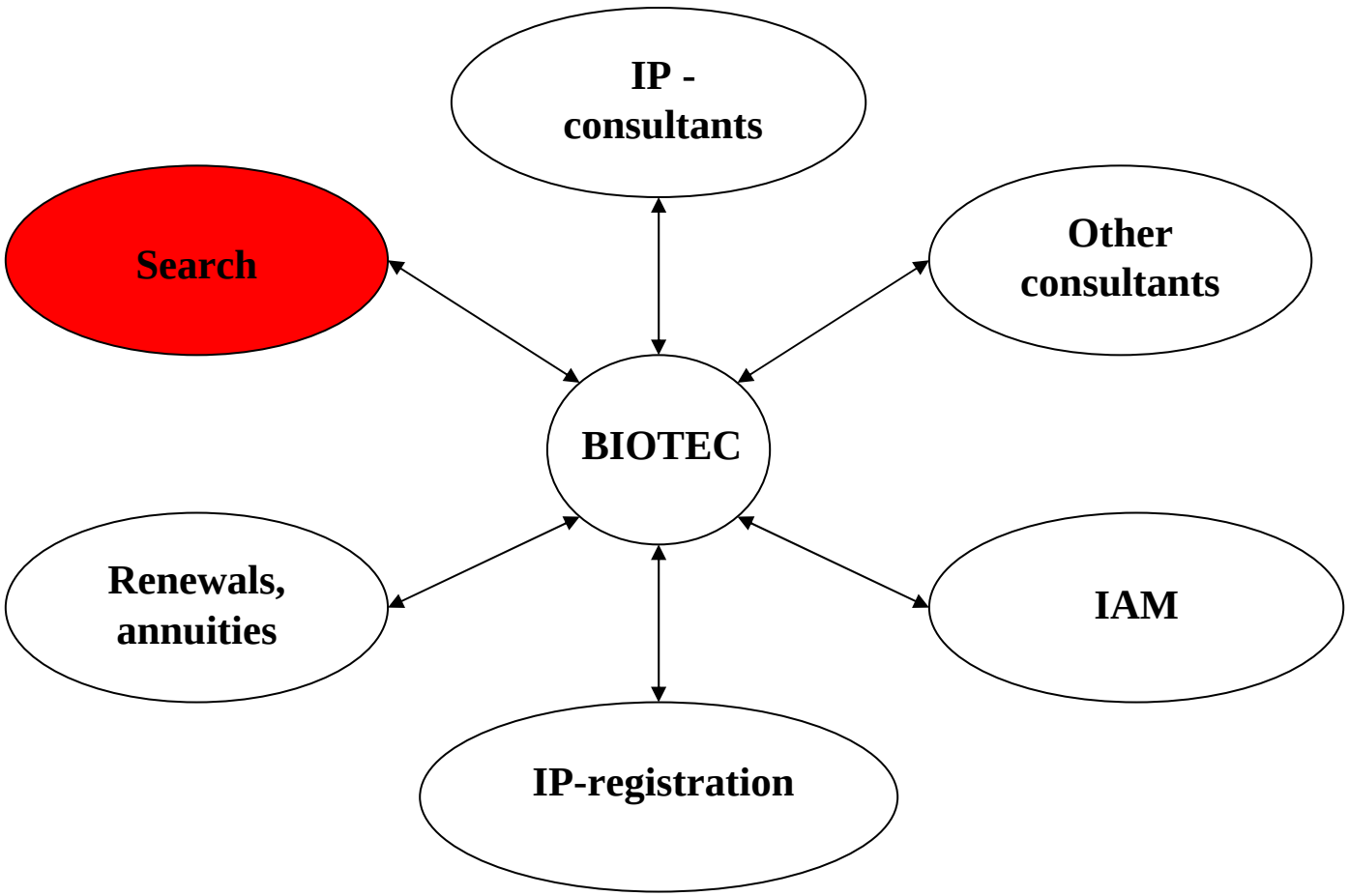
Other consultants

Examples:

- Legal (license agreements, infringement cases, globally)
- Commercialization (valuations, identification of possibilities)
- Technology (examples in patent applications, second opinions, benchmarking, producers)
- Market (royalty calculations, trends, competitive intelligence)
- Designs
- …

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Biotec Pharmacons approach –partners, tools and activities



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Search – Purpose, tools and partners

- Purpose (Novelty / IS-searches, infringement analysis, competitive intelligence – scientific literature, IP-publications and business information)

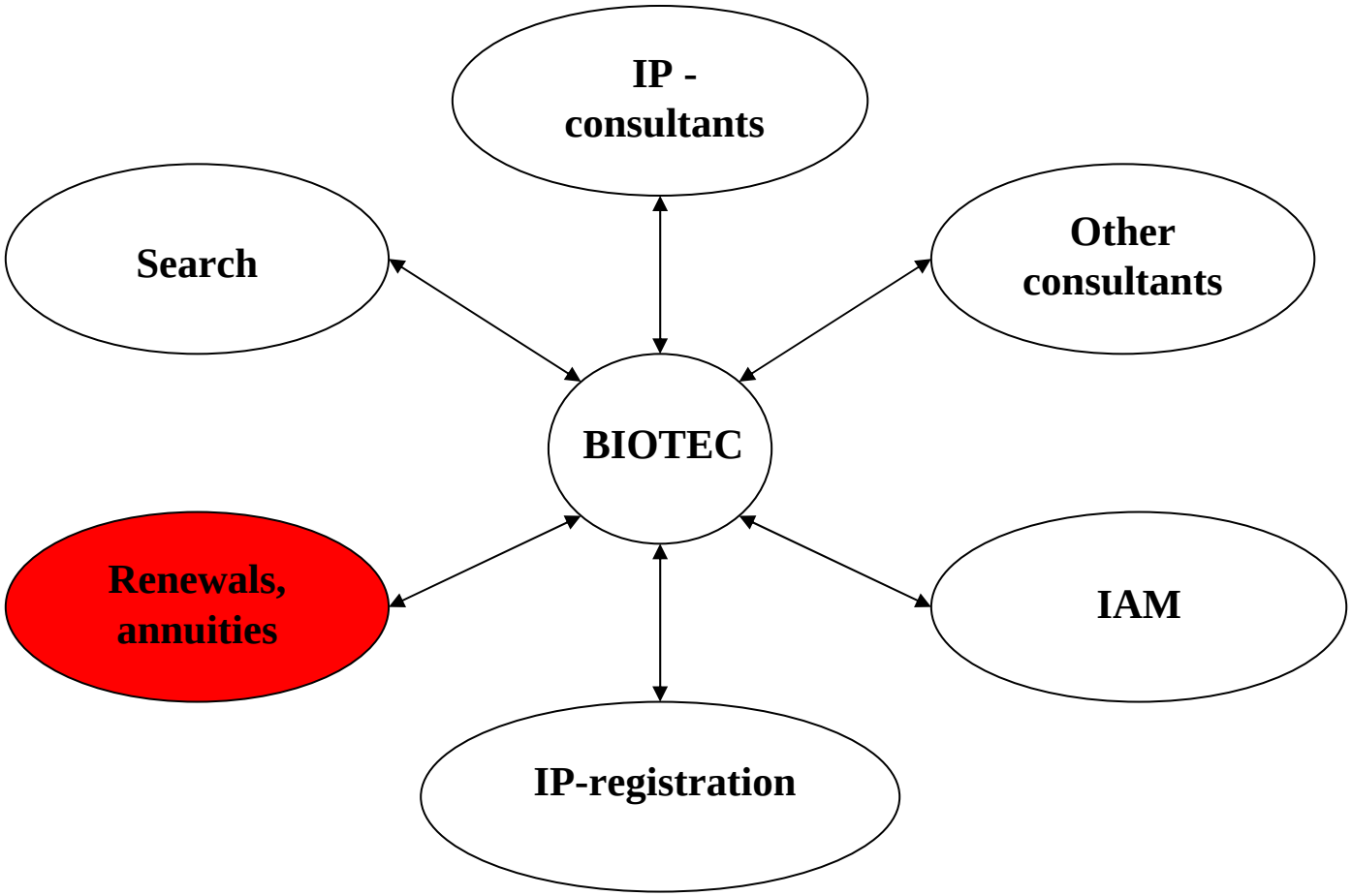
- Examples of tools – public and commercial search databases - (Micropatent, Questel-Orbit, Delphion, Nerac, BIZINT-SmartCharts, IP.com, Hoovers, Nettbased search engines (Google, Copernic,…), and other non-commercial IP/IPR databases (Espacenet, USPTO, PAJ) – Main factor: Information and price

- Examples of possible partners – evalutation of IP/IPR contents, business information and scientific literature; competitor information; purpose (defensive publishing, get an overview, …)

- A good combination: Google, Patentstyret, Delphion and Hoovers

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Biotec Pharmacons approach –partners, tools and activities



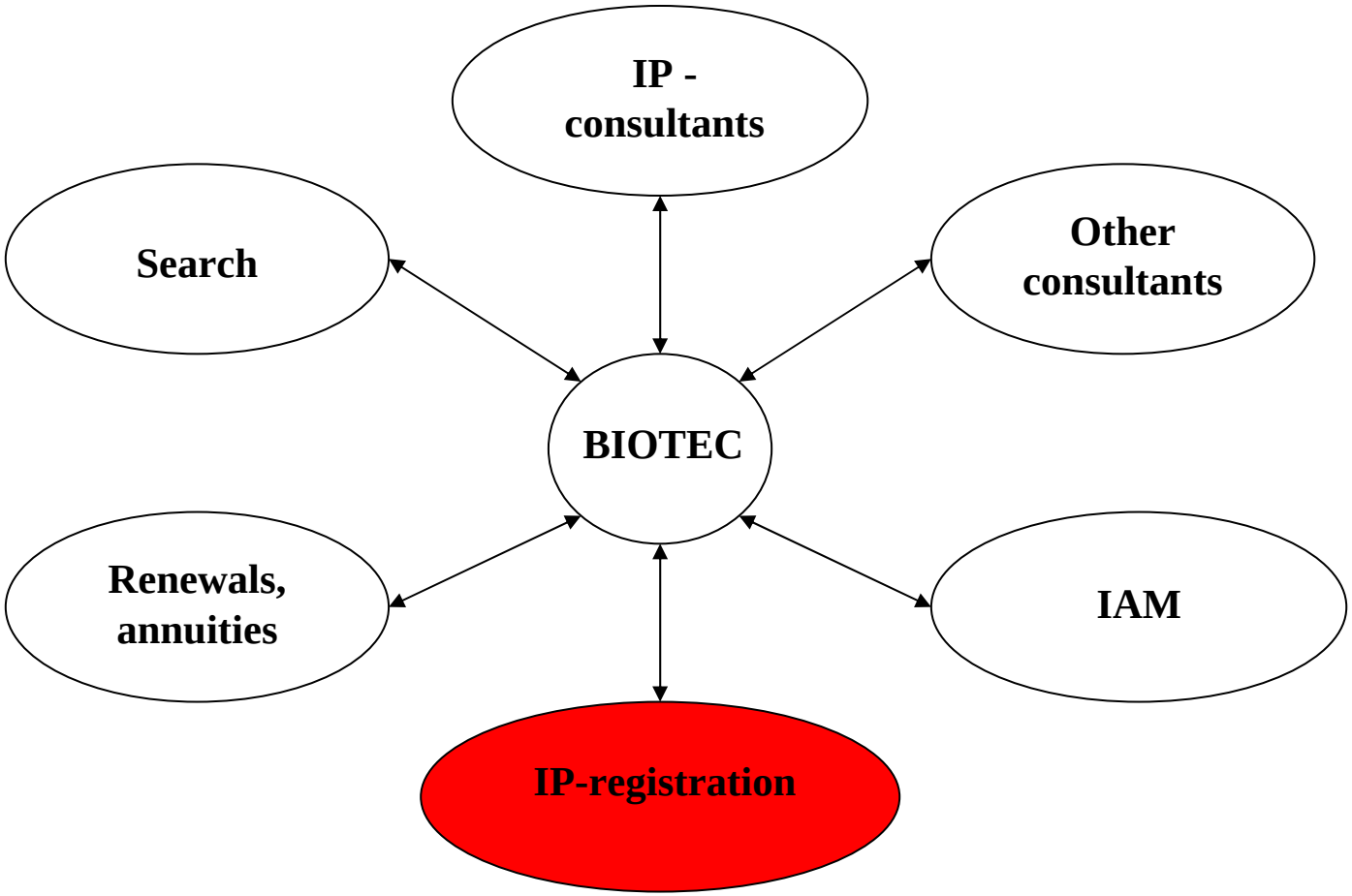
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Renewals and annuities

- Purpose: Administration and payment of annuites / renewals to secure ownership of IPR
- Choice 1: In-house / External partner
- Choice 2: External partner: IP-consultant vs. specialist
- Important: **1** service provider (easier administration, cost efficient, total overview of the portfolio)

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Biotec Pharmacons approach –partners, tools and activities



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IP-registration – Purpose and tools

- Purpose: Secure information and administrate the IP-portfolio (due dates, overview, IP(R)-Audit, IDS, communication tool)

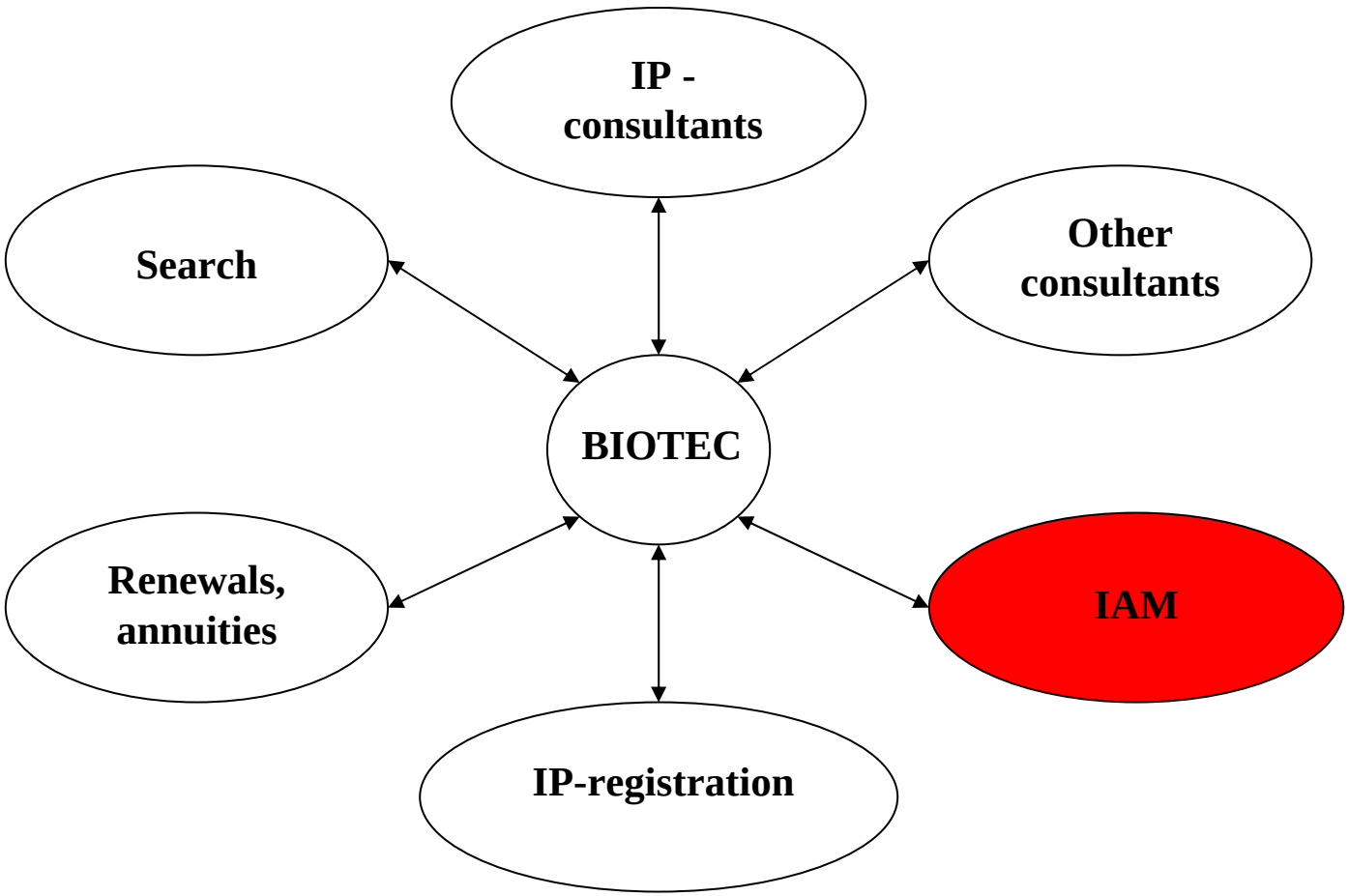
- Examples of tools: Main choice: In-house (especially with a small portfolio) contra web-based databases;

  Excel, Dennemeyer, Pattsy, InpromaCPA, First to file, Foundation IP, IPDOX, My IP, … .

- A good advice: Ask your IP-consultant regarding the use of their IP-registration system for periodic updates or for direct access (real time) to your data.

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Biotec Pharmacons approach –partners, tools and activities



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Intellectual Asset Management

Definition: “The process of maximizing the value of IP/IPR by creating a proper environment for development at Biotec Pharmacon and its business partners.”

Examples of activities:

- IP-Auditing (mining + new possibilites)
- Create a innovative environment (incentive system),
- Measuring and focusing innovation,
- Increasing of IP-knowledge to avoid troubles and see opportunities,

Possible partners / sources: (mainly internal, but …), “IP-universities”, publications (IAM), clusters, IP-discussion fora, …

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Case 1 - PeptiGard

Background: Historically **fish entrails** have been regarded as **waste products**. Today, the aquaculture industry has to pay large sums to dispose these remnants of fish processing. Within the recent years this trend turned and nowadays the **focus is on using these by-products for providing pharmaceuticals, cosmetics and health-food, as well as taste enhancers, food supplements or animal feed.**

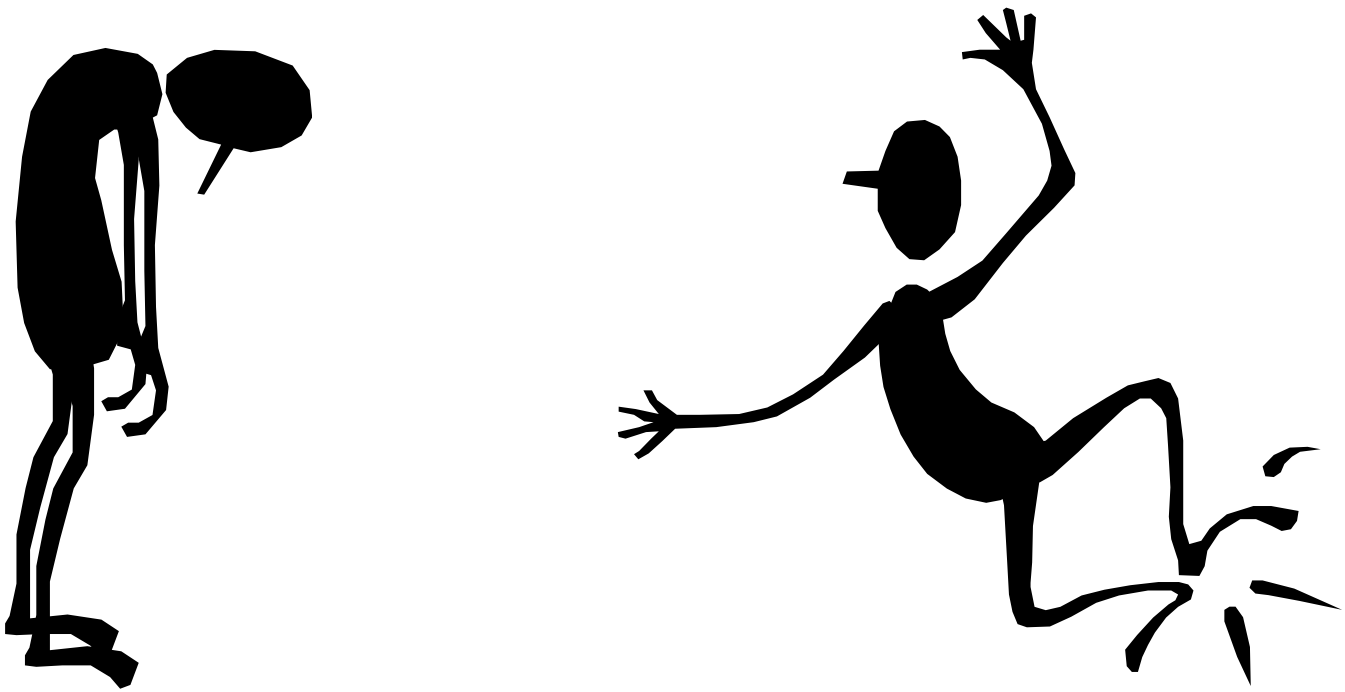
Other important factors with regard to animal feed is to **exclude at the same time hazards like for example BSE**.

Citation of our web site: www.biotec.no

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Case 1 - PeptiGard

Does not fit in our business strategy – let us commercialize it !!!



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Case 1 - PeptiGard

Questions:

1. Which alternatives would you consider to (How would you) commercialize this IPR ? (advantages / disadvantages)

   - We make a decission.

2. Based on that decission - which actions would you take to accomplish that ? (if needed, please use the figures in this presentation)

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Case 1 - PeptiGard

Your answers:

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CASE 2 - nbg®24:7™ - New products in Norwegian pharmacies



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CASE - nbg®24:7™ - History

-Immutol® (”**Immu**nity **to** al**l**”) first sold in the USA in 1997

-Immuderm® in 2000

-Sales in the USA through the internet and in Norway through the main office in Tromsø

-Continuous product development and improvement of the active ingredient

-Project launched 09.2004; since 20.09.2005 in Vitus pharmacies

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CASE - nbg®24:7™ - Background (2)

Product properties:

•Strenghtens the bodies immune defense and provides increased resistance to diseases

•Contains NBG® - one of the most effective known *immunomodulating* agents

•Extensive scientific documentation regarding effect and safety of the active ingredient

•Norwegian product – from the inside to the outside

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Thank you for your attention !

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