Life Science Licenses

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Agenda

- Why patents and licenses?
- Licenses – important tools in life science business
- IP Due Diligence First
- Case study: mRNA market players

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Why patents?

What is a patent?

- A **territorial** and **temporary** right to exclude others
  - An Austrian patent is only valid in Austria.
  - 20 years from filing, at max.

- **A patent in one country is independent of a patent in another country (national patent law).**
  - In countries without patent protection, the invention can be used by anyone.
  - In countries with patent protection, the invention can only be used by a licensee with a permission of the licensor - LICENSE

How to exploit a patent?

Biotech companies typically share value with partners

Development/ commercialization partners – <u>codevelopment / outlicensing agreement</u>

- upfront/milestone payments, royalty income
- commercialization rights in certain territories

Financing community – <u>transaction</u>

- private financing round
- public offering
- merger & acquisition

Patenting / Partnering is key to meet corporate growth goals

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When it comes to patents, we mean business

Get patents

Get business value / opportunities / money

Patents are key for technology monetization

- License revenue (upfront, milestone, royalty payments)
- Funded R&D collaboration
- New start-up opportunities (Spin-out)
- Financing by public funds, investors (VC, business angel)

In return, the partner gets access to patent protected technologies / product candidates

What is a license?

A *licensing* agreement is a contract that allows one party (the *licensee*) to use and/or gives permission to another party to use *patent*, know-how, … of the patent proprietor (*the licensor*)

“Biotechnology has become a primary driver of product and technology innovation and has become a cornerstone in new product development by all biopharma companies”
(Evens R.P., The AAPS Journal, Vol. 18, No. 1, January 2016)

“The operating budget of the Weizmann Institute of Science is around **1.5 billion NIS** per year. A third of this funding comes from the government of Israel. The rest of the Institute’s income is generated through scientific discoveries, competitive grants, private philanthropy, and scientific services offered by Institute core facilities to academic and commercial partners. **Scientific discoveries generate significant income from licensing agreements made through Yeda, the Institute’s technology transfer arm**.”
(https://wis-wander.weizmann.ac.il/about/facts-figures?page=9)

A license is a business tool to drive innovation, to earn money.

How to earn money
Köhler & Milstein – monoclonal antibodies

Inventors of hybridoma technology at MRC (Cambridge, UK)

NRDC (responsible for patenting MRC inventions):
„no practical application“

→ No patent was filed
→ Publication in *Nature* 1975
→ Nobel Prize 1984

Milstein
'We were too green and inexperienced on the matter of patents‘

→ Later, Wistar (US) filed and marketed „use patents“
(anti-tumor, anti-Influenza Virus)

MRC has learned its lesson

Greg Winter: **Nobel Prize 2020** on phage display of peptides and antibodies

Plus:

Based on Greg´s inventions:

MRC received patents on antibody humanization and license revenues

Plus:

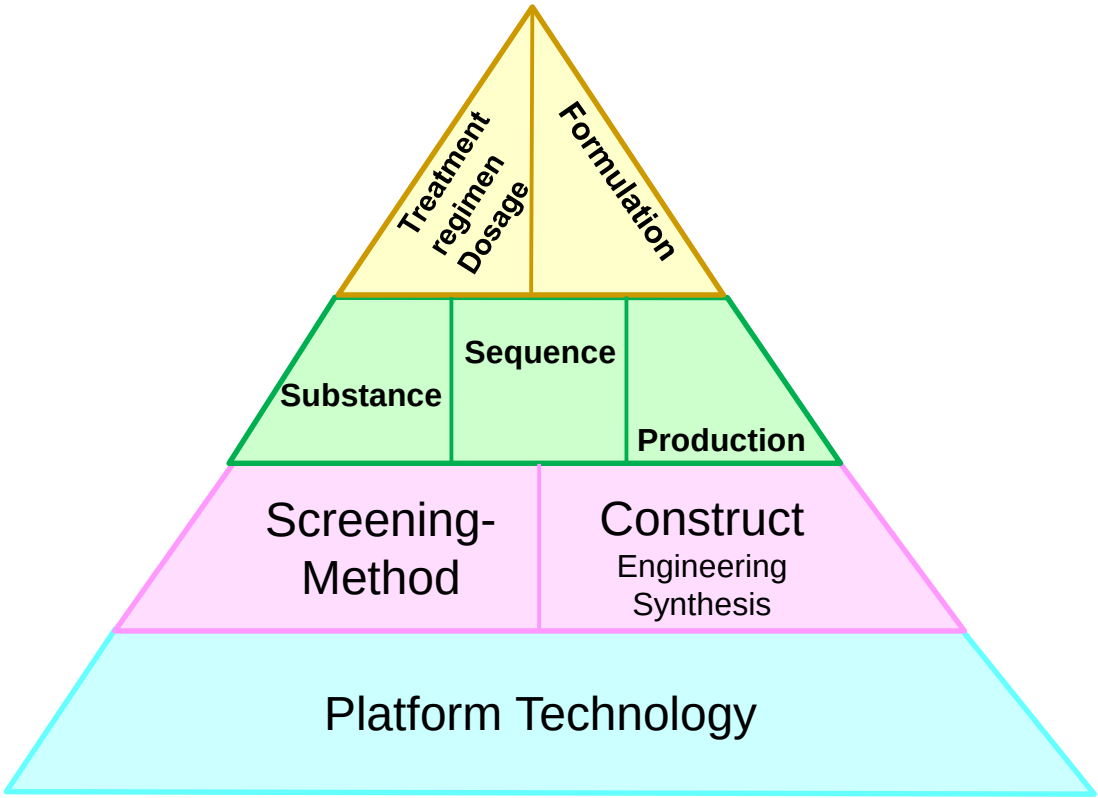
Greg started companies based on patent protected technologies and products: CAT, Domantis, Bicycle Therapeutics

License revenues

- 2014: The MRC received income of £40m from intellectual property, most of it related to monoclonal antibodies — out of a total budget of £771.8m.

- Patent cliff: IP revenue dropped to £5m in 2016-17 because of patent expiry.

One patent to license – is it enough?



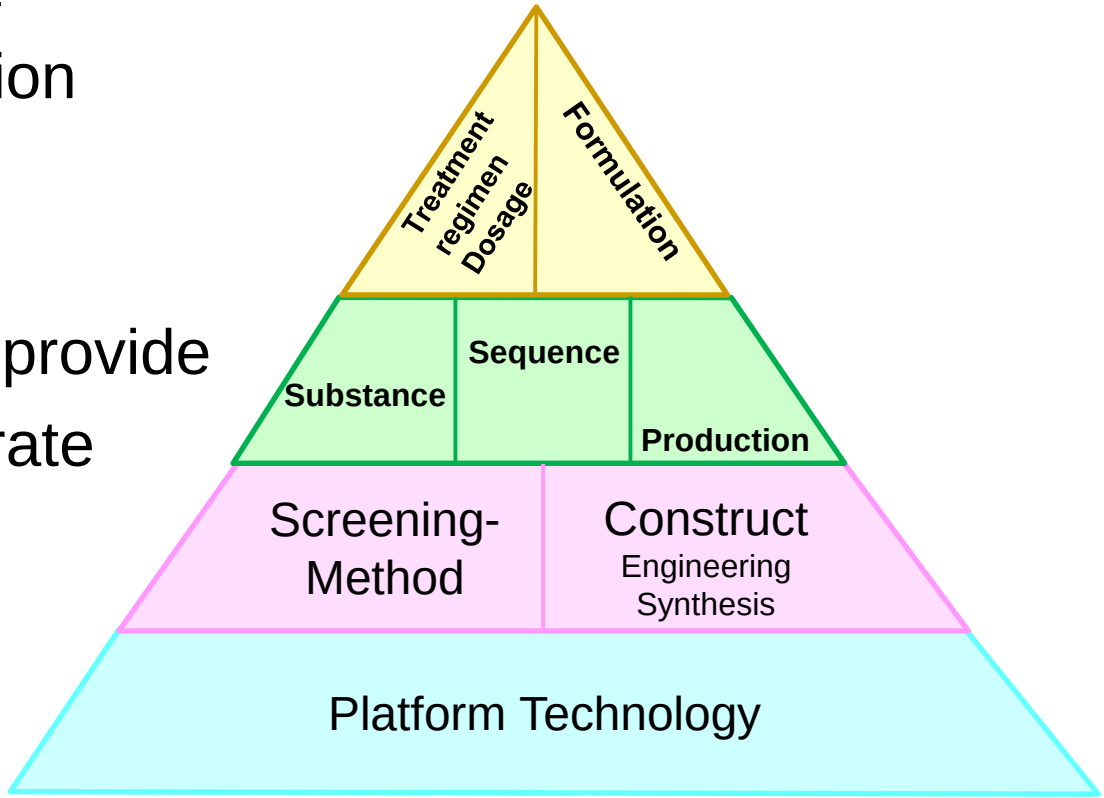
Your patent portfolio

Your claims protect

- against competition
  (me-too)

Your claims do not provide

- Freedom-to-operate
  (FTO)



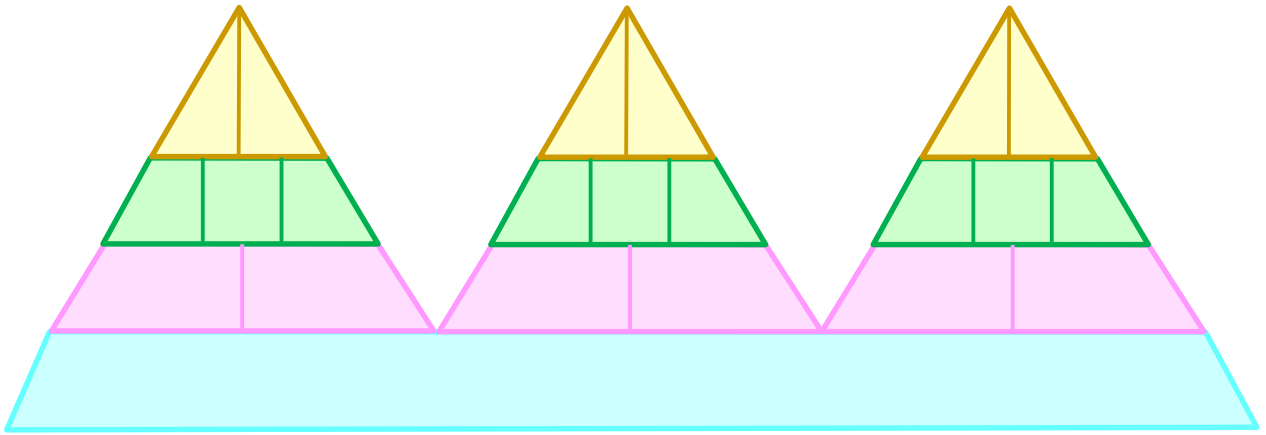
Which is your patent situation?

Shark tank questions
“Have you got a patent on that?”
“Has anyone else a patent on that?”

Is your product / technology covered?

Others have patents as well

„this is a crowded field“



Licensing in and out – many questions

You seek for a potential development / business partner?
You find your claims infringed?
What do you want from a licensee?

- Money
- Rights in return, cross-license?

Is there a business opportunity for you?
Starting with existing IP?
Is there an issue with FTO?

- Licensing?
- Working around?
- Wait for patent expiry in selected territories?
  - Meanwhile clinical studies are possible (“Bolar exemption“)
- Opposition/ invalidation?

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Find your way

Business opportunities

- Inlicensing
- Outlicensing
- Strategic alliances
- Manufacturing, supply and distribution agreements
- Joint Ventures
- Spin-Outs
- Mergers, acquisitions or divestitures
- …

In any case, beware of IP issues
→ IP Due Diligence

IP Due Diligence First

License out:

„IP Due Diligence ready“ – find and sanitize issues and be prepared to convince the licensee‘s IP counsel

License in:

„IP Due Diligence“ – know what you buy: validity of patents of interest and FTO, risk adjusted financial structure

Then go for the appropriate terms of contract:

- Products, enabling technology (platform), tools
- Exclusive/ non-exclusive
- Worldwide/ regional
- Sublicensable, transferable
- Financials: royalties / annual fees / milestone payments

Case: mRNA Licenses In and Out

The University of Pennsylvania exclusively licensed certain mRNA patent rights to CellScript and its affiliate, mRNA RiboTherapeutics, on December 20, 2016.

CellScript further entered into non-exclusive worldwide sublicenses with Moderna on June 26, 2017 and with BioNTech on July 14, 2017.

In addition, a license was granted to the NIH (registered 2012)

"a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States"

Special interest of the NIH:

The technology was developed by Drew Weissman and Katalin Kariko of Penn's Perelman School of Medicine.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT The invention described herein was supported in part by grants from The National Institutes of Health (Grant No. AI060505, AI50484 and DE14825). The U.S. Government may have certain rights in this invention

The Trustees of the University of Pennsylvania EP2578685B1 and US8278036B2 (and others)

EP2578685B1

1. An ex vivo or in vitro method for inducing a mammalian cell to produce a functional protein of interest, the method comprising the step of contacting said mammalian cell with in vitro -synthesized modified RNA encoding a protein of interest, wherein said in vitro -synthesized modified RNA comprises the modified nucleoside pseudouridine.

11. A composition comprising an in vitro -synthesized modified RNA as defined in claims 1, 2, 3 or 9.

(EP divisional pending)

US8278036B2

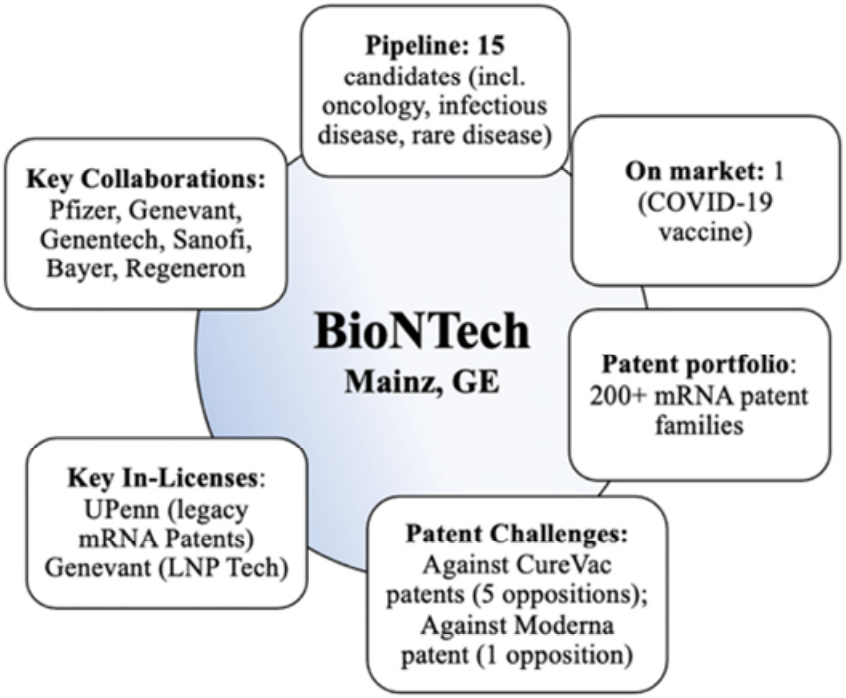
1. A method for inducing a mammalian cell to produce a protein of interest comprising: contacting said mammalian cell with in vitro-synthesized modified RNA encoding a protein of interest, wherein said in vitro-synthesized modified RNA comprises the modified nucleoside pseudouridine.

BioNTech case

BioNTech SEC info: its overall worldwide owned and in-licensed patent portfolio includes more than 200 patent families, at least 100 of which are solely or jointly owned by BioNTech.

mRNA patent portfolio including patents and applications directed to mRNA structures (e.g., for increased immunogenicity), mRNA formulations (e.g., lipolex formulations, lipid nanoparticles), mRNA manufacturing (e.g., mRNA purification and production), and mRNA product candidates (directed to various indications including oncology, infectious disease, rare disease).

Source: Daniel Shores & Dylan Haversack & Andrew J. Storaska, Ph.D. April 11, 2021; https://www.rothwellfigg.com/publications/the-mrna-ip-and-competitive-landscape-through-one-year-of-the-covid-19-pandemic



Moderna case

Moderna SEC info: over 270 issued or allowed U.S. and foreign patents protecting mRNA-based technology, with over 600 worldwide pending patent applications; at least seven granted U.S. patents protecting its COVID-19 mRNA-1273 vaccine.

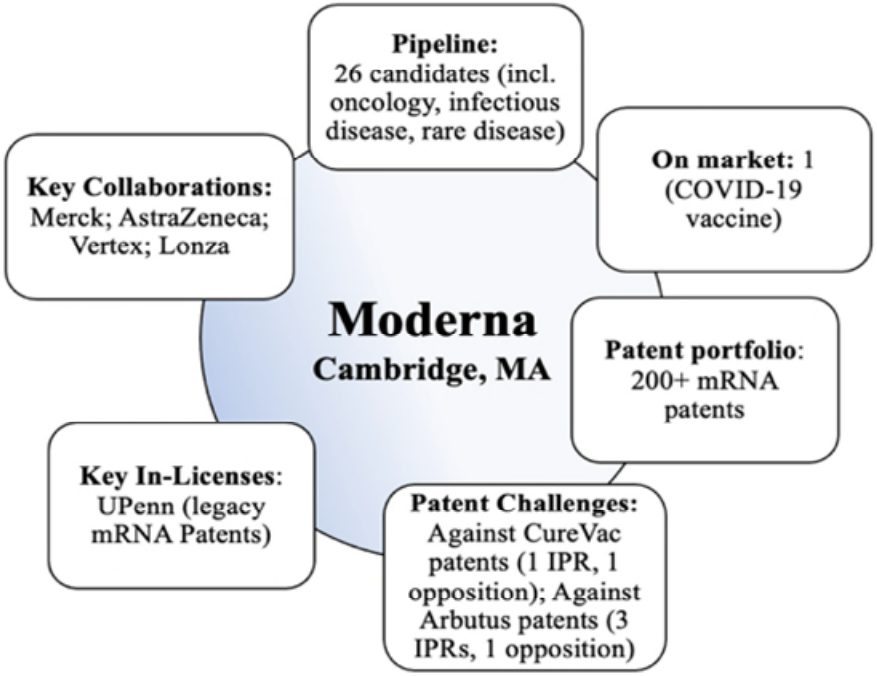


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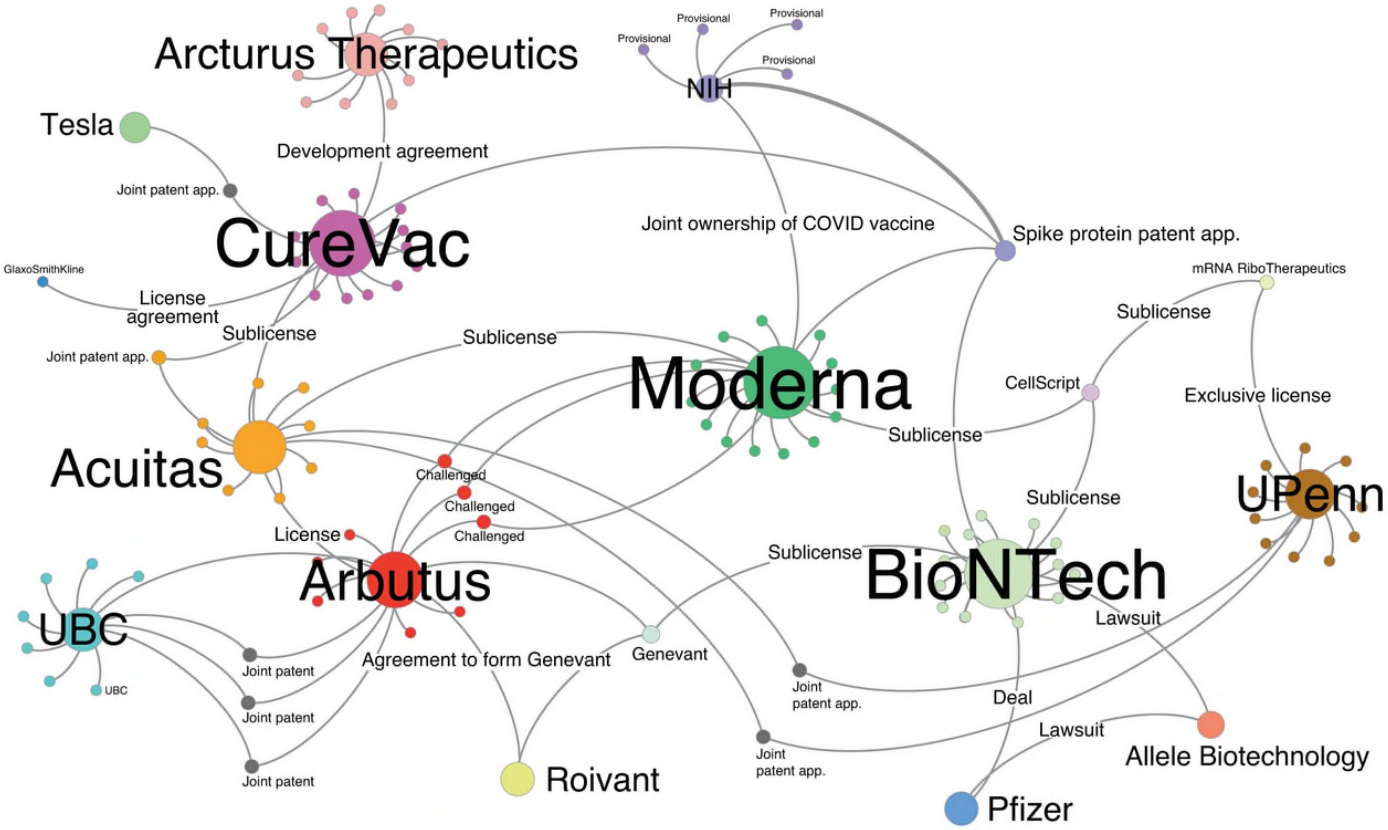
Fig. 1: Patent network analysis of mRNA-based vaccine candidates for COVID-19.

From: A network analysis of COVID-19 mRNA vaccine patents



Large nodes represent the relevant entities while the edges represent agreements or patents between two entities. Smaller nodes around the entities represent patents that were identified as being relevant to the underlying vaccine technology (Supplementary Information). The network analysis was developed using Gephi[23]. UPenn, University of Pennsylvania; UBC, University of British Columbia; app., application.

Source: Gaviria, M., Kilic, B. A network analysis of COVID-19 mRNA vaccine patents. Nat Biotechnol 39, 546–548 (2021). https://doi.org/10.1038/s41587-021-00912-9

Challenges of the COVID-19 pandemic

- **Open COVID Pledge – in place**

Makes patents and copyrights freely available in the fight against the COVID-19 pandemic (mostly IT, social media and AI fields); American University Washington College of law

- **COVID-19 Technology Access Pool (C-TAP) – in place**

Costa Rica's proposal to create a pool of rights to tests, medicines, and vaccines, with free access or licensing on reasonable and affordable terms, supported by WHO, limited use

- **Compulsory licenses – WTO/TRIPS, implemented in national law**

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) signed by all 164 WTO member states, Art. 31

Governments can enforce access to the vaccine and authorize themselves, or third parties, to make use of a patent without the permission of the patent owner through "compulsory licensing" in case of a national emergency, if the holder of a patent does not give away patent rights voluntarily – adequate remuneration required.

- **Temporary TRIPS IP Waiver – under discussion**

Initiated by South Africa and India (supported by 60 WTO members, incl. limited support by USA) to suspend IP protection for products and technologies in the fight against COVID-19.

When it comes to patents, we mean business

THANK YOU FOR YOUR ATTENTION!

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