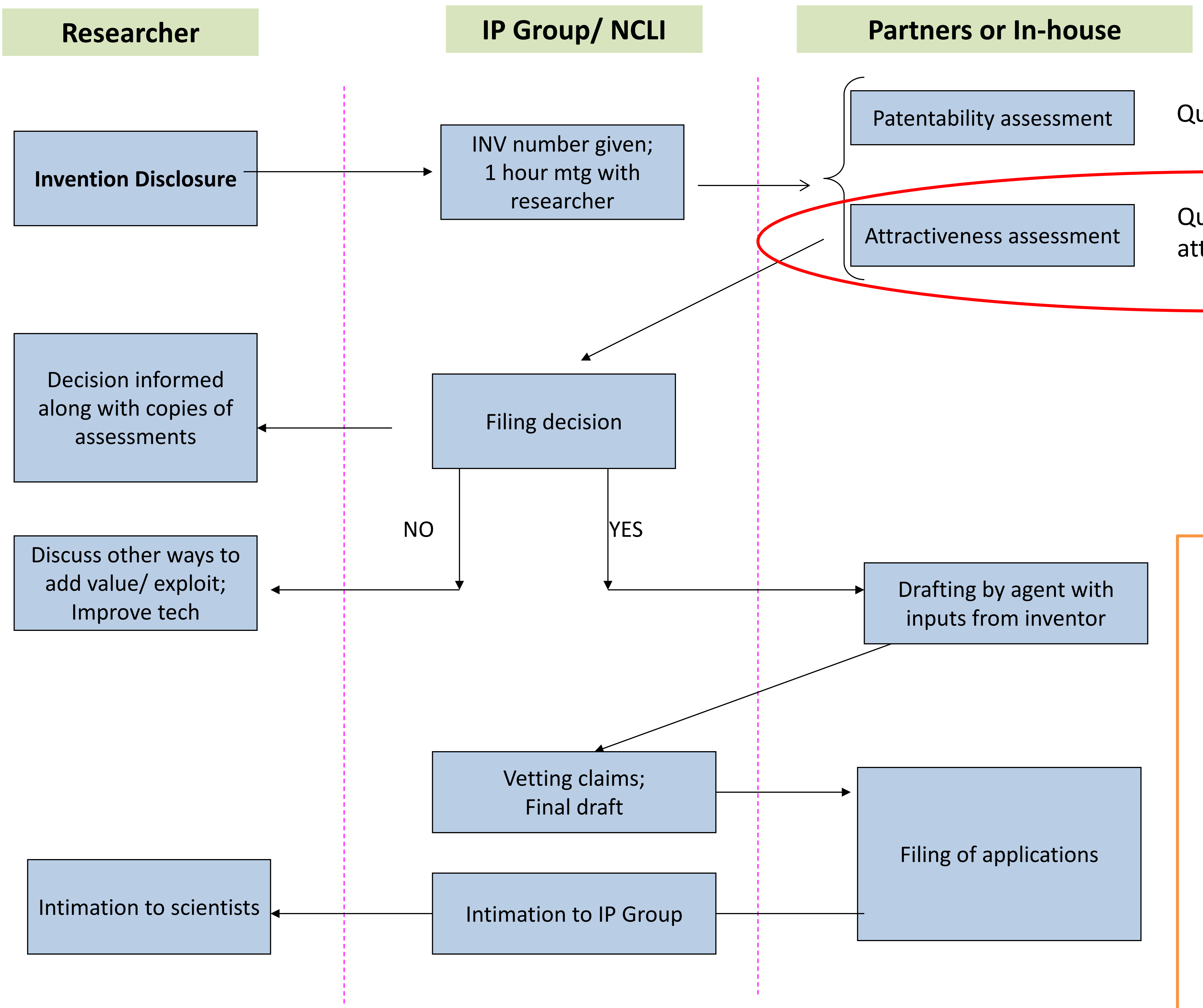
Assessing an Invention for IP Strategy

Premnath V, PhD
Head, NCL Innovations | Founder Director, Venture Center
7 June 2024 | Workshop @ TechEx.in

Reminder: NCL's patent document flow and decision points



Question: Is it patentable?

Question: Is it commercially/ strategically attractive ? Is it worth filing?

Note: This should be done only when the effort is justified by the investment risk involved?

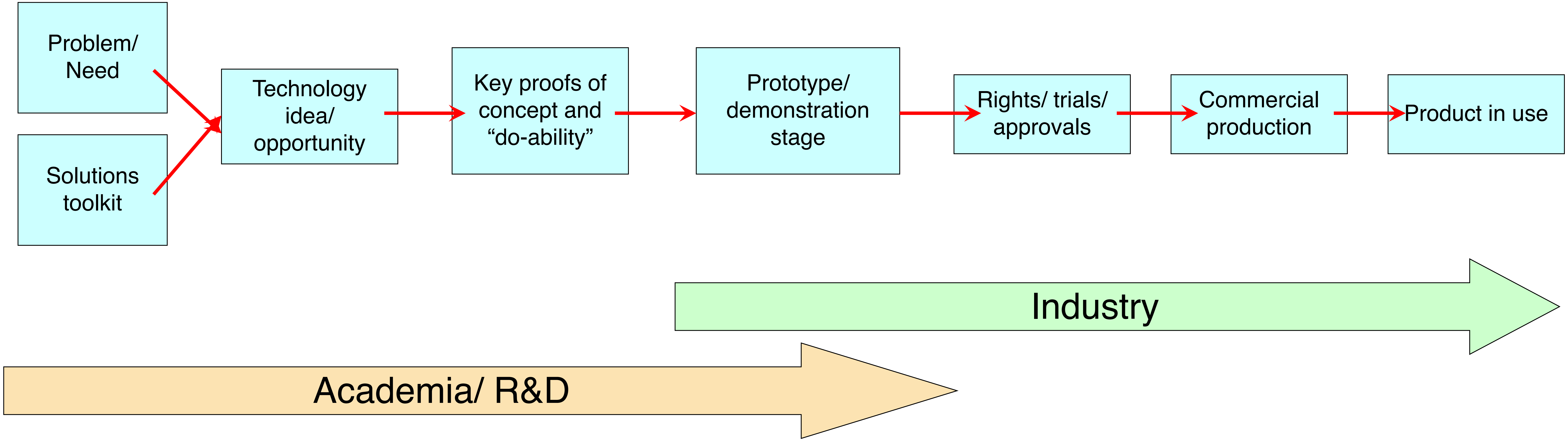
Example: JHU Tech Ventures

https://ventures.jhu.edu/technology-transfer/reports-of-invention/

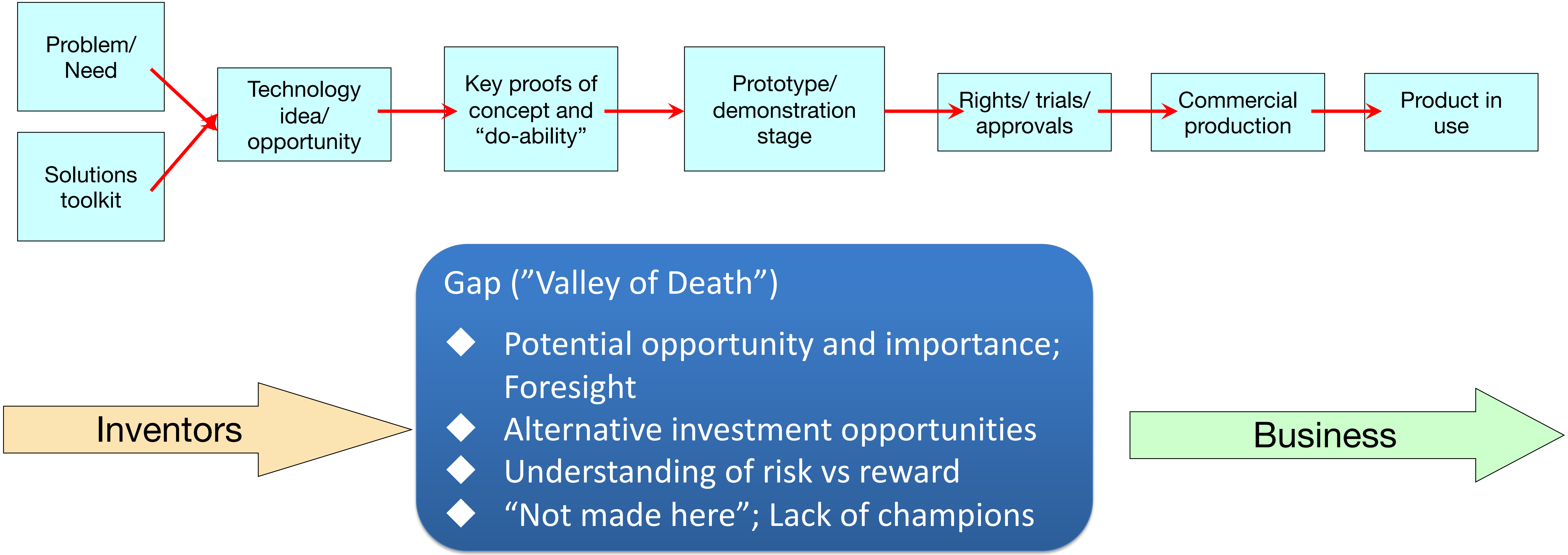
Our Commitment to Service: 2-2-2

2 Days	2 Weeks	2 Months
JHTV will contact you within **2 business days** of receiving your disclosure.	JHTV will confer with you regarding your disclosure within **2 weeks** of receiving your disclosure.	JHTV will provide a written determination within **2 months** about the commercialization plan.

Classical technology transfer



The gap: Interests, motivations, expectations, trust



Outline

Outline:

- ❖ Walk through the First Look Assessment
- ❖ Exercise: First Look Assessment for an Invention

- ❖ Understanding the invention (problem, solution, novelty)
- ❖ Understanding potential customer segments & end product
- ❖ Understanding the value proposition against alternatives for customer segment
- ❖ Understanding the opportunity
- ❖ Understanding the risks, uncertainties, competition
- ❖ Understanding the status/strength of the technology and IP
- ❖ Understanding what KOLs/experts have to say
- ❖ Thinking through path ahead and strategy

Walk through the First Look Assessment

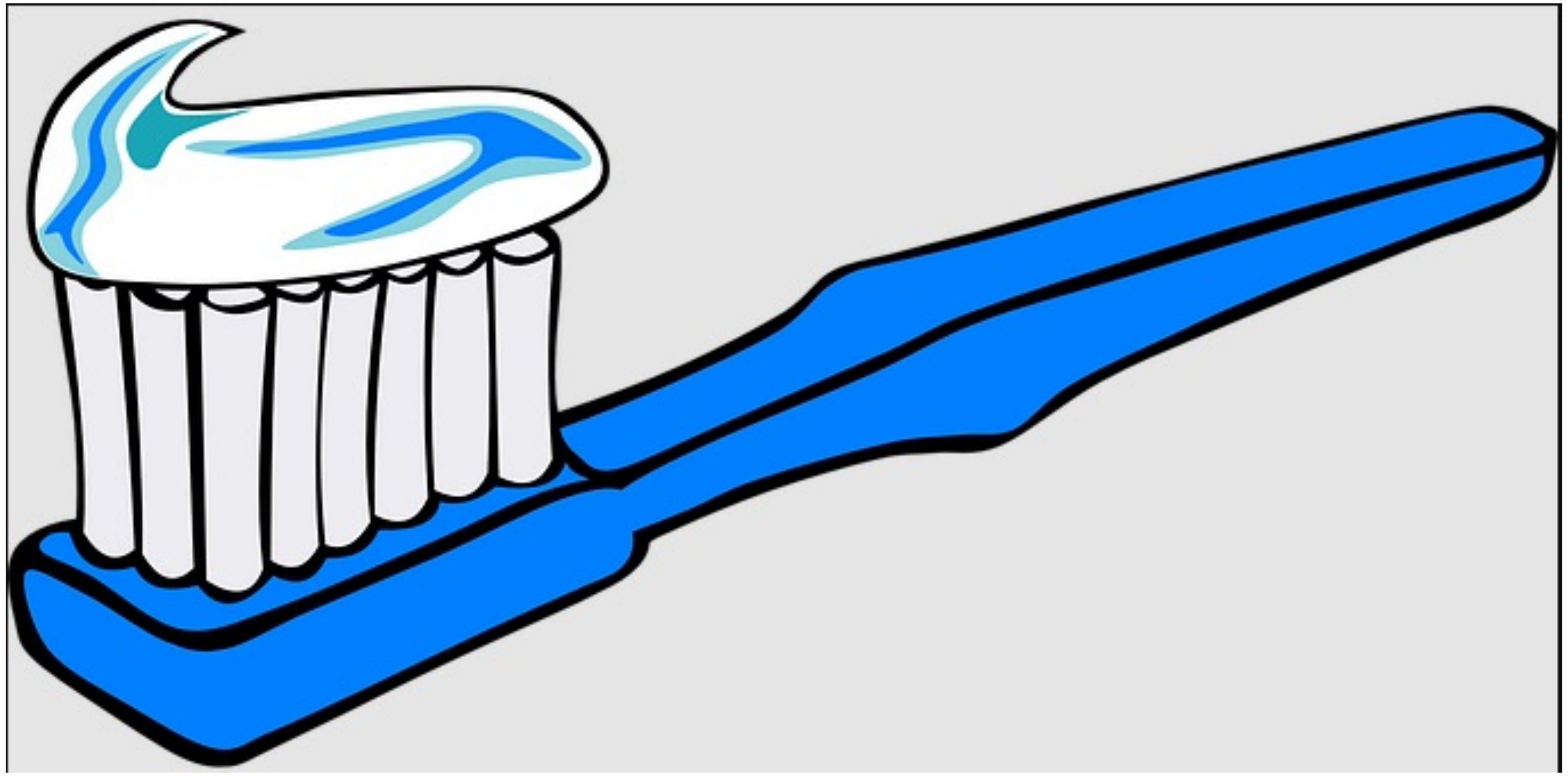
See Handout and template given to you

Outline:

- C1. General information
- C2. Inventor's description of the invention/ technology and related inputs (based on interview with inventor)
- C3. Case manager's description of the invention/ technology in a problem-solution approach and comparison with alternative solutions
- C4. Translation to end-products and assessment of technology
- C5. Inputs from interviews with peer experts/ industry professionals/ potential customers/ licensees/ KOLs
- C6. Summary assessment and recommendations

Exercise: First Look Assessment for an Invention

Exercise: The “special” tooth brush



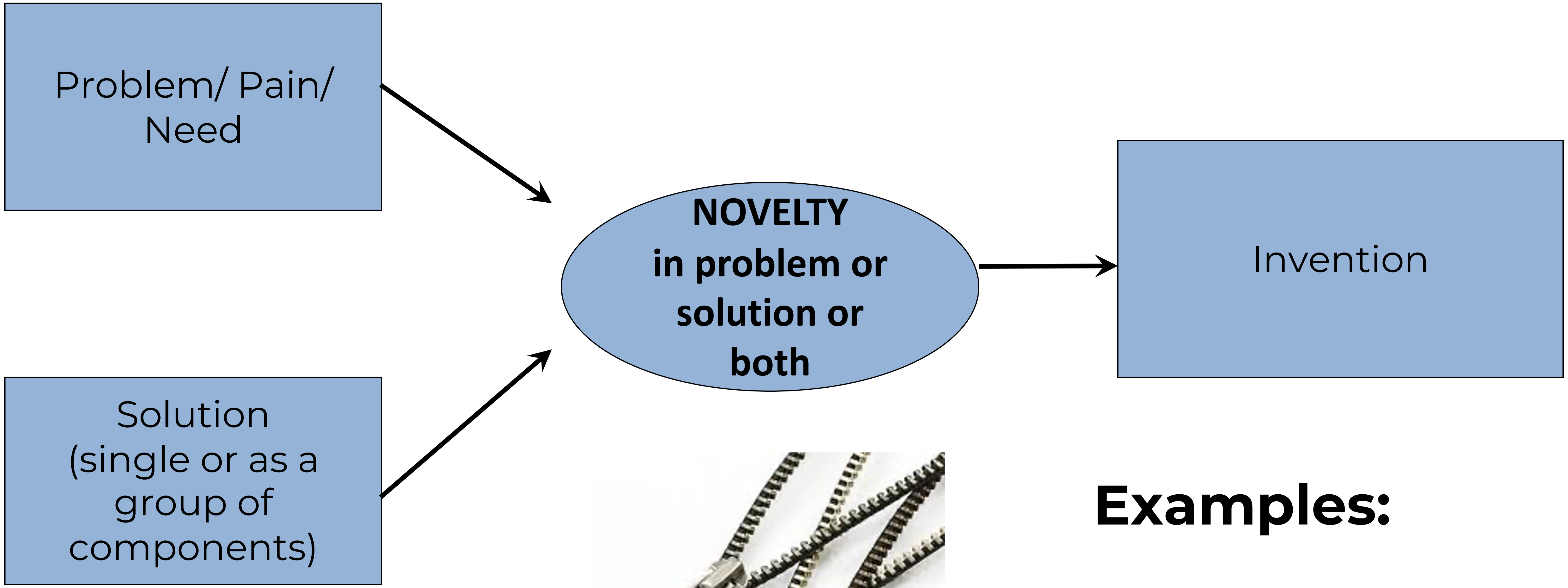
Documents for Toothbrush Example

- Indian patent

- CCAMP's Technology Brief

Problem, Solution, Novelty

Invention



Examples:

-- Zip/ Velcro/ Bundling tie

-- (Science-led) Vaccines, drugs

Example: Need statement

- A way to perform rapid, point-of-care testing for C19 in travelers in order to identify and restrict movement of C19 carriers.

Example: Deep dive

- Mapping:
  - Let us focus on high-volume transport, esp. air travel.
  - Entry → departure → security → boarding → flight --> baggage → arrival → Exit
  - Who is having a need? (GoI or Pune city or travellers) What is the need?
- Comparison of alternatives:
  - Pre-certificates, thermal screening, visible symptoms, rapid test, RT-PCR
  - Compare for time, cost, false negatives, false positives, stage of infection

Example: Problem definition

- There is a need for a 30 min rapid RT-PCR for airport departure lounges to rule out C19 carriers with 100% accuracy.
  - Use case: Airports (esp departure lounges??)
  - Rapid: 30 min
  - Key outcome: Zero false negatives (a person who is positive should not slip through as negative)
    - Notice assumption of a solution: Only RT-PCR can do it

Exercise 1: Problem definition

Name:

A way to do what?	
For whom	
To achieve what outcome	
Currently available ways/ approaches to deal with the problem	
Short comings of current alternative approaches	

Ref: Based on the Need Identification process of the Stanford Biodesign Program

Potential Customer Segments and End-Products

Customer offering

Product visualization

Customer offering will consist of	
Features	
Price	

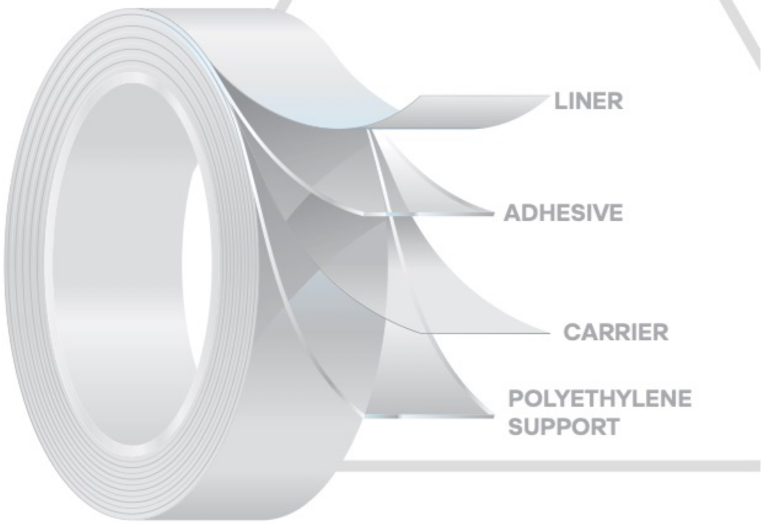
https://medical.averydennison.com/content/dam/medical/medicalproducts/TDS/tds_med-5589h.pdf

TECHNICAL DATA SHEET

MED 5589H

Hydrocolloid

MED 5589H



MED 5589H is a transparent polyurethane film containing an advanced and integrated hydrocolloid formulation. This product's absorbent adhesive is designed to not break down upon saturation, provides a low profile, assists in creating optimal skin and wound healing conditions and has a high fluid handling capacity.

TYPICAL APPLICATION

Designed for wound care applications and fixation of medical devices.

FEATURES AND BENEFITS

- Conformable
- Integrated hydrocolloid
- High absorption rate
- Moisture resistant
- Die-cuttable
- Gamma sterilizable

Product Construction

	TYPICAL VALUES*		DESCRIPTION
SUPPORT THICKNESS	1.0 mils	25 µm	Transparent polyethylene film
CARRIER THICKNESS	1.8 mils	45 µm	Transparent polyurethane film
ADHESIVE THICKNESS	23.6 mils	600 µm	Hydrocolloid designed for medical applications
RELEASE LINER THICKNESS	5.1 mils	130 µm	White super-calendered glassine

TECHNICAL DATA SHEET

MED 5589H

Hydrocolloid

MED 5589H

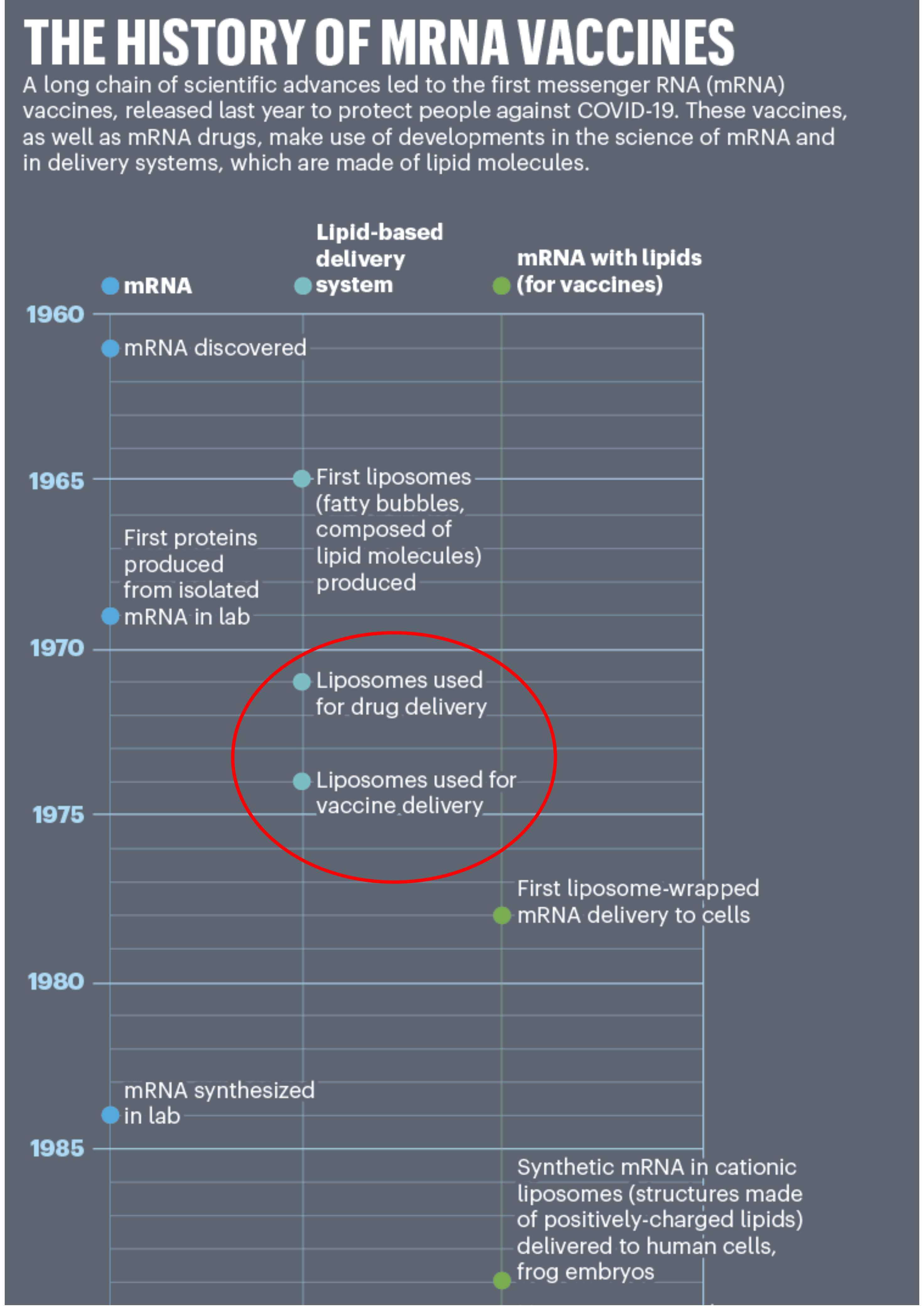
Physical Properties [Not intended as specification]

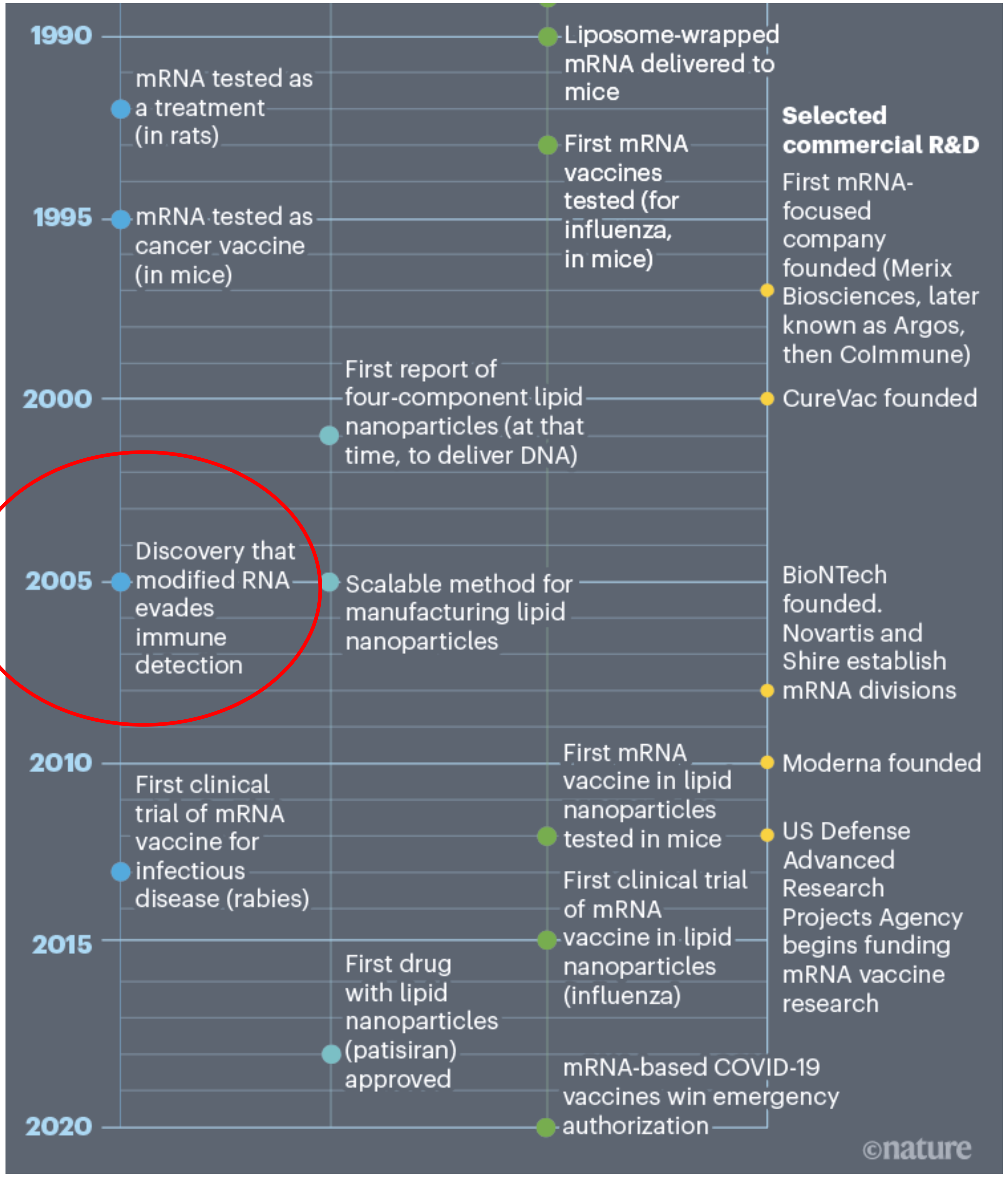
	TEST METHOD*	TYPICAL VALUES†	
PEEL ADHESION ON POLYETHYLENE	TDS-02	0.5 lbf/in	2.0 N/25 mm
PEEL ADHESION ON STAINLESS STEEL	TDS-03	1.3 lbf/in	5.5 N/25 mm
LINER RELEASE	TDS-06	2.9 oz/in	50 g/25 mm
REVERSE TACK	TDS-09	3.7 lbf/in	16 N/25 mm
STATIC SHEAR	TDS-14	2300 minutes	
MVTR	TDS-17	23 g/100 in² per 24 hr	350 g/m² per 24 hr
STATIC ABSORPTION	TDS-17	304 g/100 in² per 24 hr	4710 g/m² per 24 hr

MVTR, moisture vapor transmission rate.
*Test method information available upon request.
†Refer to product specifications for material acceptance limits.

mRNA Vaccine

Source: https://www.nature.com/articles/d41586-021-02483-w





Inventors are important!

But technology commercialization champions are key!

Dr. Drew Weissman (U Penn)
Dr Katalin Karikó (UPenn; RNARx; BioNTech)

Inventors: Non-immunogenic, nucleoside-modified RNA

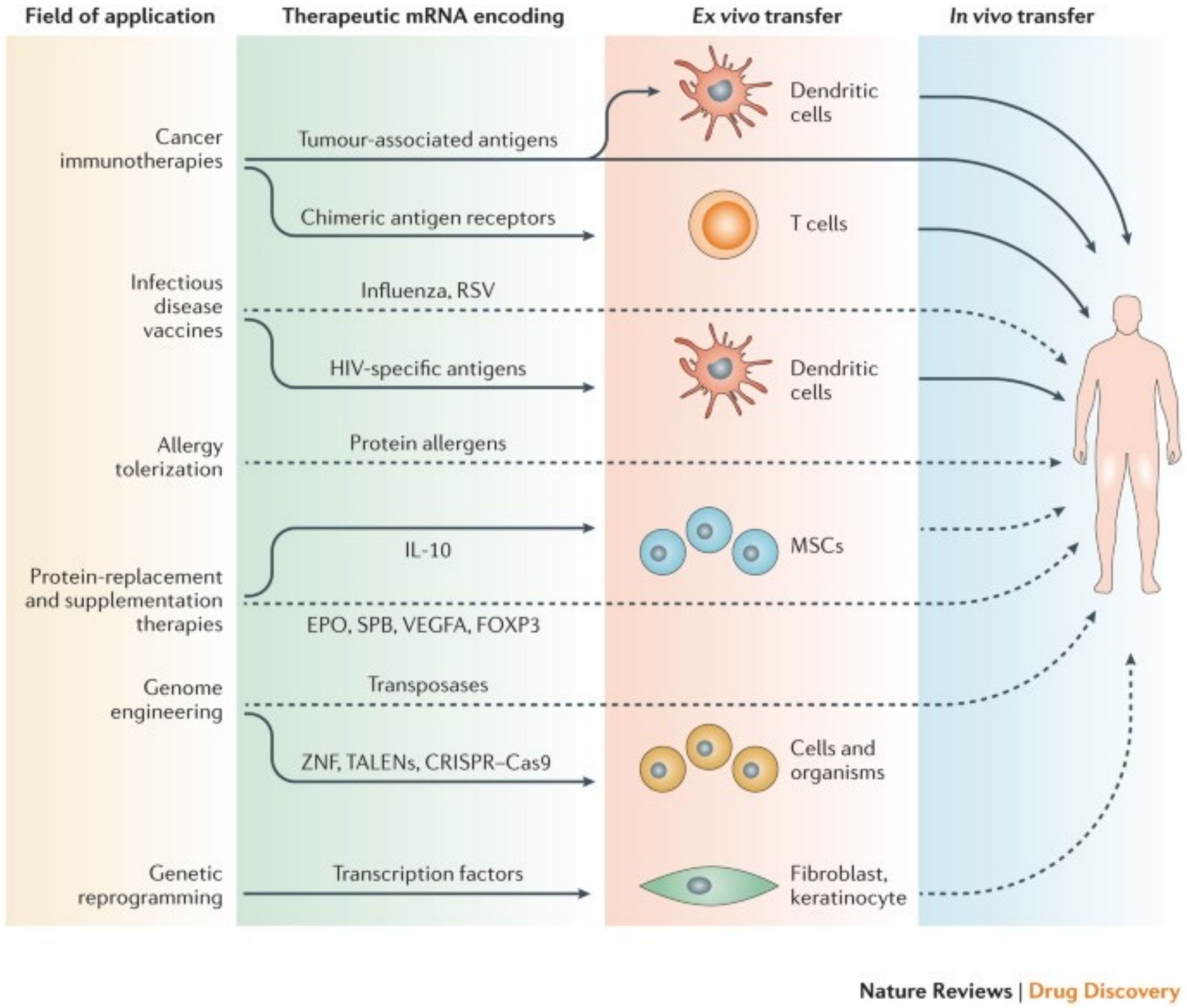
Lasker Award 2021; Breakthrough Prize 2021; Nobel 2023

https://edition.cnn.com/2021/09/24/health/lasker-awards-mrna-weissman-kariko/index.html

Özlem Türeci (left) and Uğur Şahin (right) co-founded the mRNA vaccine firm BioNTech

https://www.nature.com/articles/d41586-021-02483-w

Exercise: mRNA technology



https://www.nature.com/articles/nrd4278

nature reviews drug discovery

Explore content ⌄ About the journal ⌄ Publish with us ⌄

nature > nature reviews drug discovery > review articles > article

Review Article | Published: 19 September 2014

mRNA-based therapeutics — developing a new class of drugs

Ugur Sahin, Katalin Karikó & Özlem Türeci

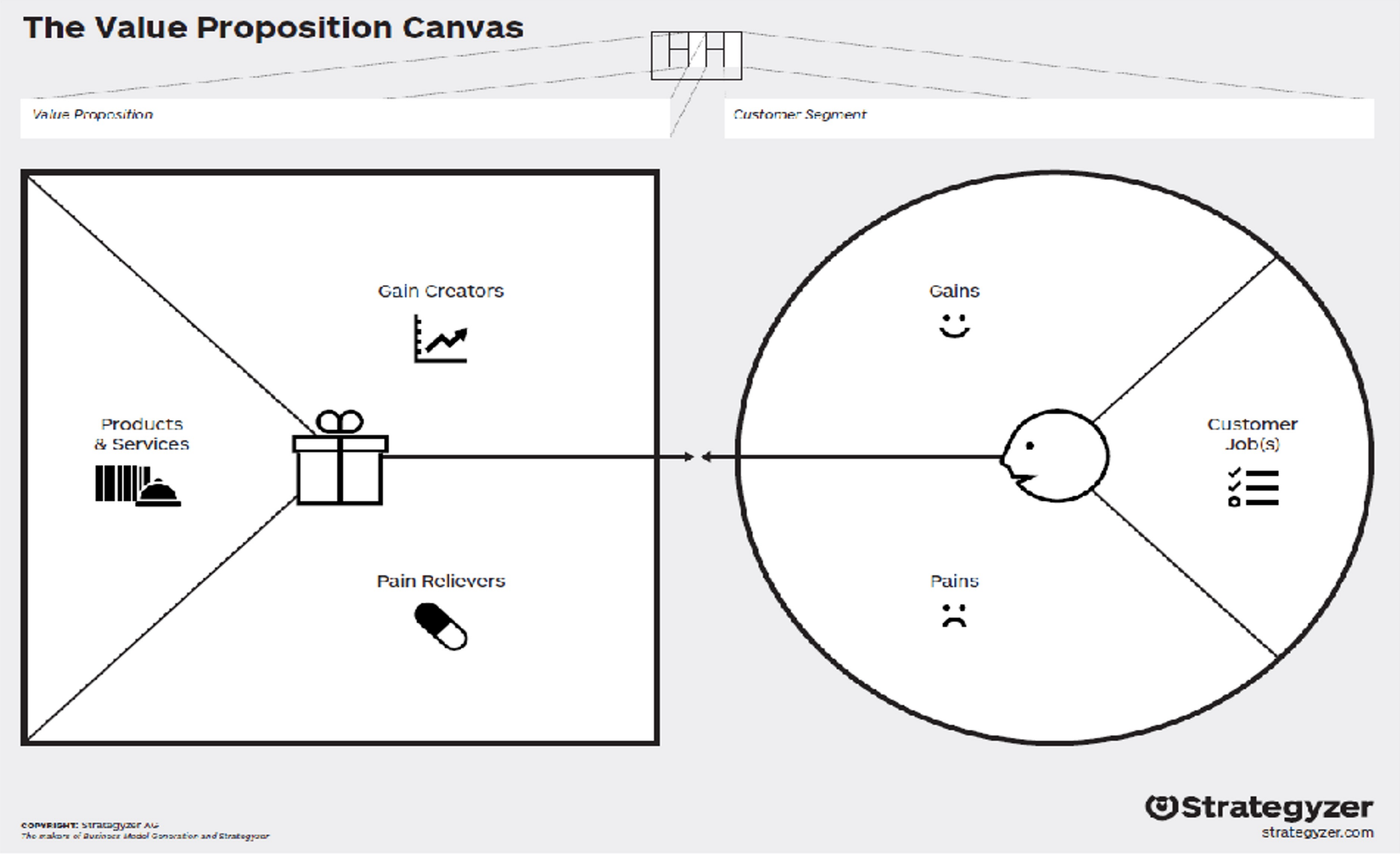
Nature Reviews Drug Discovery **13**, 759–780 (2014) | Cite this article

Value Proposition

What is a Value Proposition?

Source: Anonymous. Internet

A FRAMEWORK TO DESIGN VALUE PROPOSITION

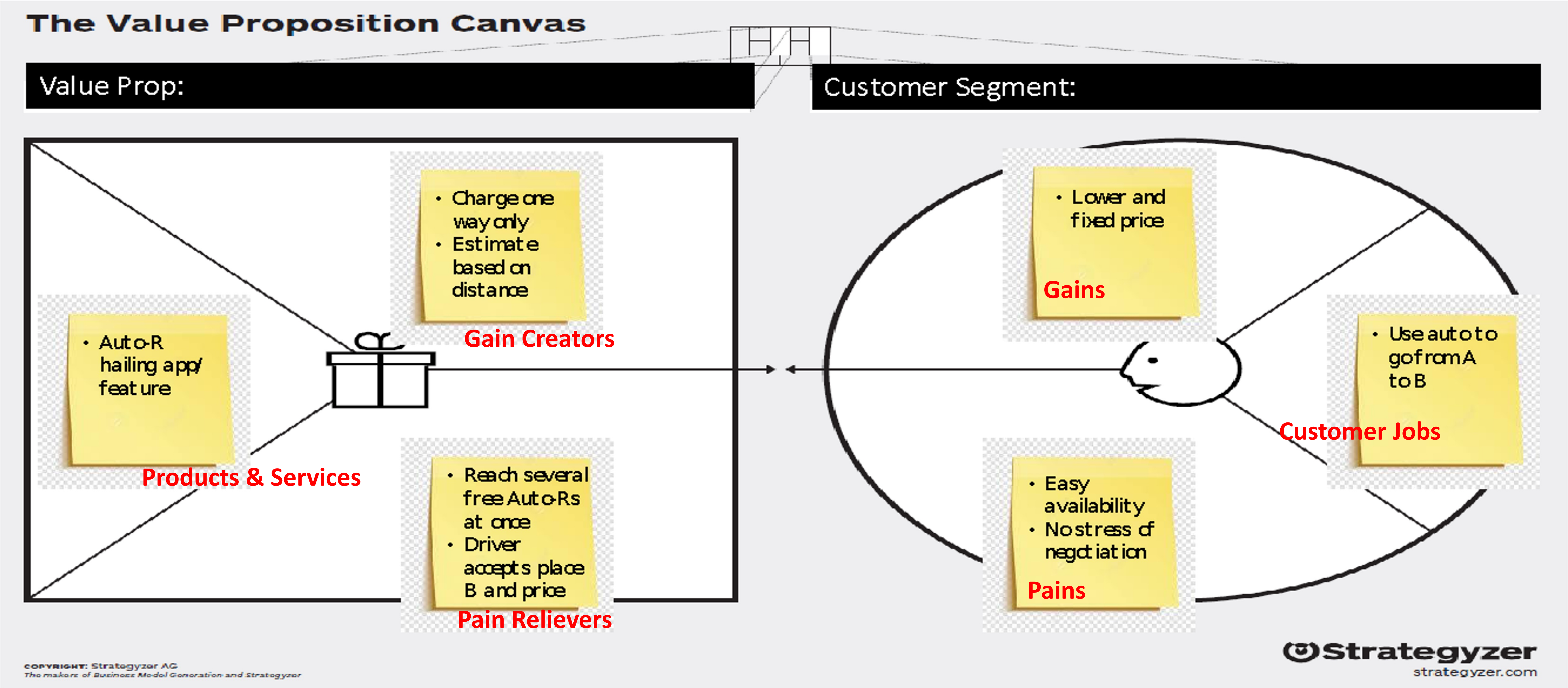


- You can start either side of the canvas; but starting with Customer Jobs (Customer Journeys) makes it easier
- Know the Customer's functional, emotional and social needs.
- Try to be as quantitative as possible
- Focus on one User Persona in each canvas--(N = 1) approach
- User – Customer mapping is essential
- Don't confuse jobs (=activities, processes) and outcomes (=results)
- Keep unit economics in context

Courtesy: Sundara Nagarajan, IndusAge

INDUSAGE SCALEUP ADVISORS

AN EXAMPLE OF VALUE PROPOSITION MAP: AUTO-RICKSHAW HAILING APP



Courtesy: Sundara Nagarajan, IndusAge

Strengthening Value proposition

- Take one customer category at a time
- List benefits for that customer category from all product offerings in that category including yours; be careful in selecting the alternatives. They have to the right ones, relevant and important ones that the customer segment can recognize as currently available.
- What does the product do? - Product vs. Technology, Key value vs. added values
- Compare the benefits (not "features" or "properties" but benefits; You can have a column of features that make the benefits possible)
- Where do you really stand out? Is it important for your customer?
- Where are you unsure? What are uncertain? What experiments do you need to do to illustrate superior benefits to customer? Features, data sheets, price points to demonstrate your claims (DE-RISKING STUDIES!)
- What will be acceptable to the customer as reliable evidence of superior benefits?

Exercise 3: Value proposition

Name:

3. Customer offering/ product	7. Gain creators (Features)	8. Gains	1. Customer segment
4. Alternatives/ competing products	6. Pain reliever (Features)	5. Pains	2. Desired customer outcomes

Ref: Based on Value Proposition Canvas by Strategyzer.com

Exercise 2: Comparison

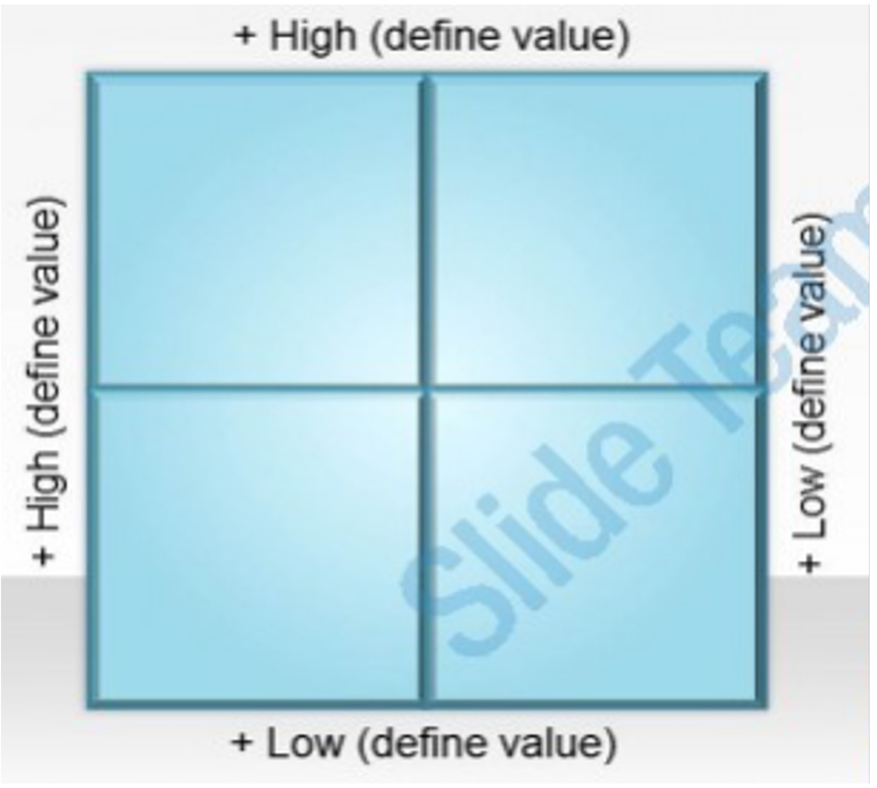
Name:

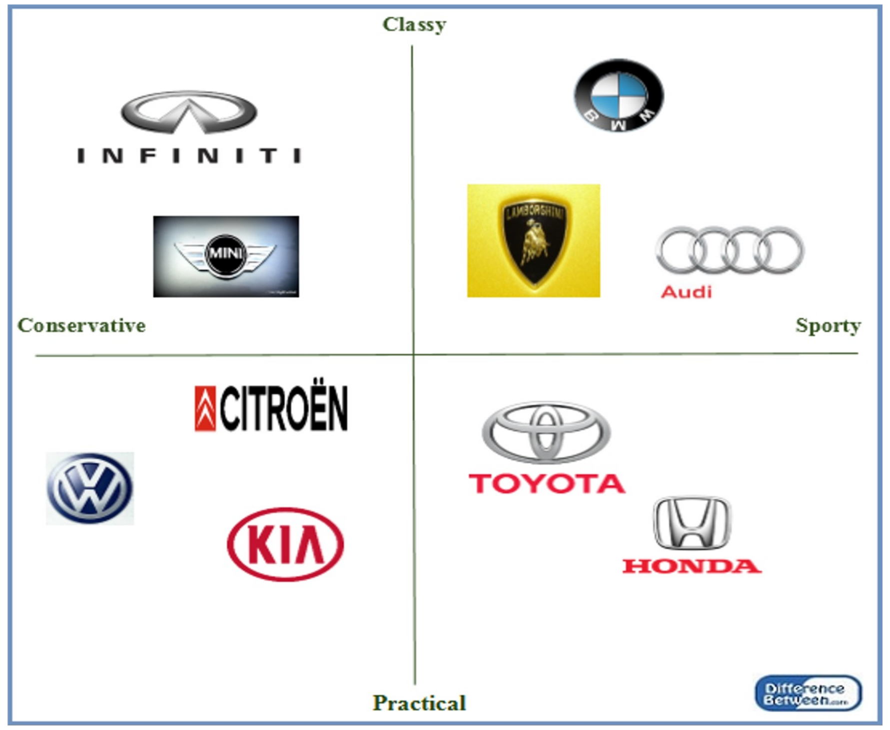
Alternatives -> Benefits (Gains/ Pains) | V			

Product Comparison Chart

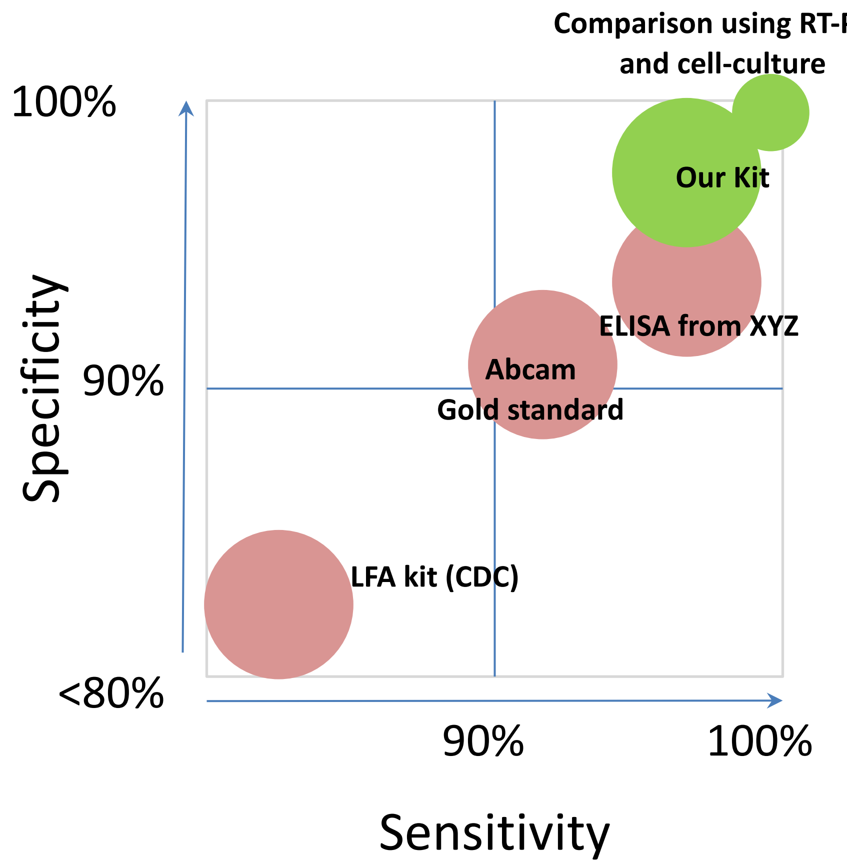
	Polyolefin	ABS	PLA	Nylon	PC
Water and Moisture resistance	+++	-	-	-	+++
No odours or harmful emissions	++	-	++	+	-
Impact Performance	+++	+	-	+++	++
Durability	++	++	-	++	+++
Hardness	+	++	++	+	+++
Ease of Use	++	+	+++	-	-
High Temperature Resistance / Softening Temperature	++	++	-	+	+++
Economical Print Temperatures	+++	-	++	+	-
Recyclability	+++	-	+	+	+

Positioning Charts





- ❑Diagnostic – Specificity vs. Sensitivity
- ❑Battery – power vs. energy
- ❑Fertilizer – cost vs. yield
- ❑Drug – Efficacy vs. side effects



The opportunity

Opportunity analysis

- Existing market
  - Market Research (Secondary, Primary)

- Emerging market
  - Project a scenario of the future and project market opportunities; KOL opinions

- Strategic opportunities: Have options available (ex: Fuel cells R&D at NCL; vaccines during C19)

- Tactical opportunities: Place on the negotiation table, negotiate prices

- Funding/ investment opportunities: Ex – having multiple pieces of knowhow and IP in those spaces – say, mRNA modification, LNP; say, applications of CRISPR

Risks, uncertainties, competition

Competition

https://hbr.org/2008/01/the-five-competitive-forces-that-shape-strategy

https://hbr.org/video/3590615226001/the-explainer-porters-five-forces

https://www.business-to-you.com/porters-five-forces/

Selected Risks/ Uncertainties

Key risks to usage/ commercialization

- ❖ Technical/ scale-up/ manufacturability risks
- ❖ Freedom to operate/ IP risks
- ❖ Regulatory/ standards/legal hurdles
- ❖ Market risks
- ❖ Industry/ competition risks
- ❖ Financial/ scale of investment barriers

Status/strength of the technology and IP

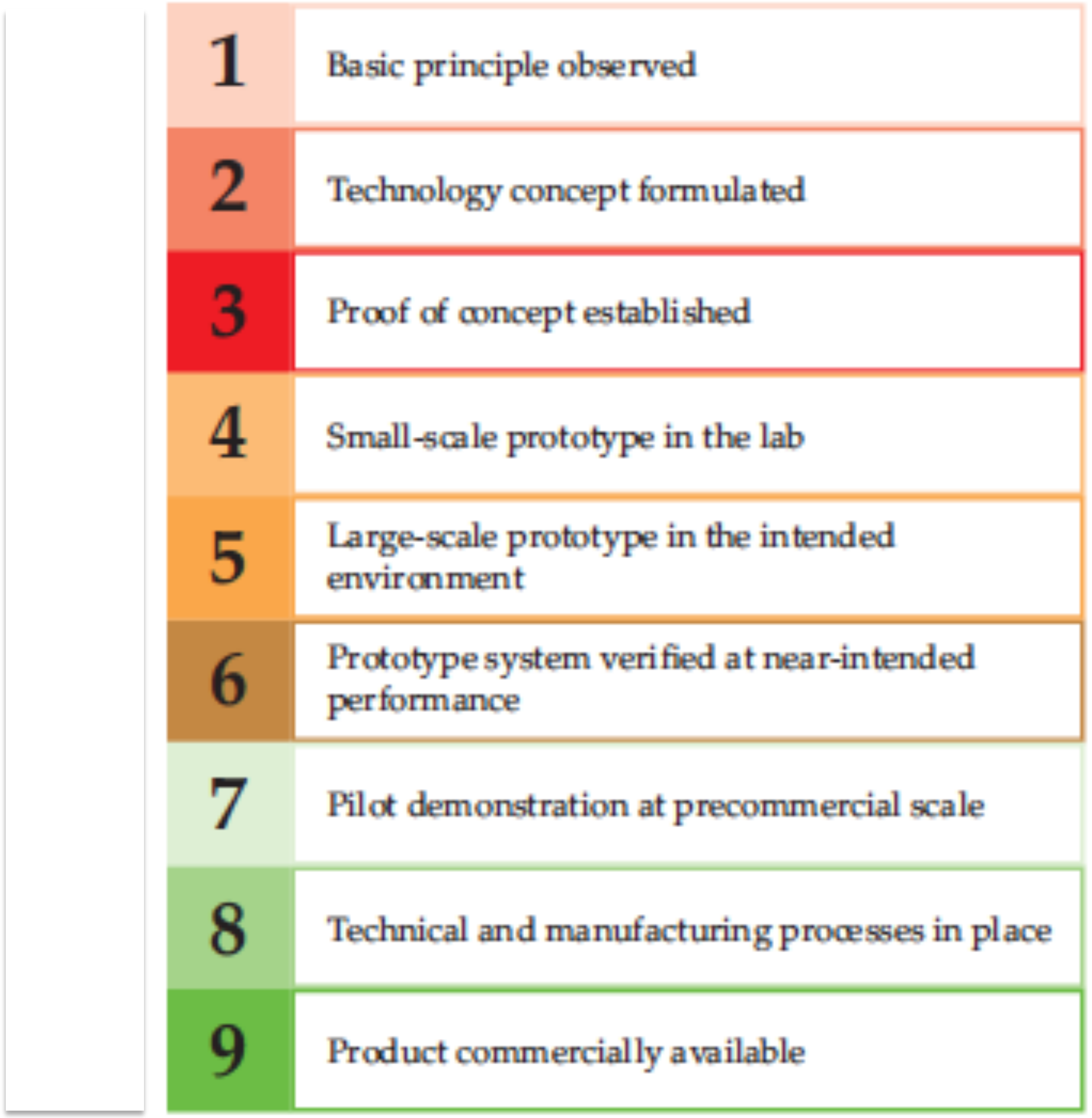
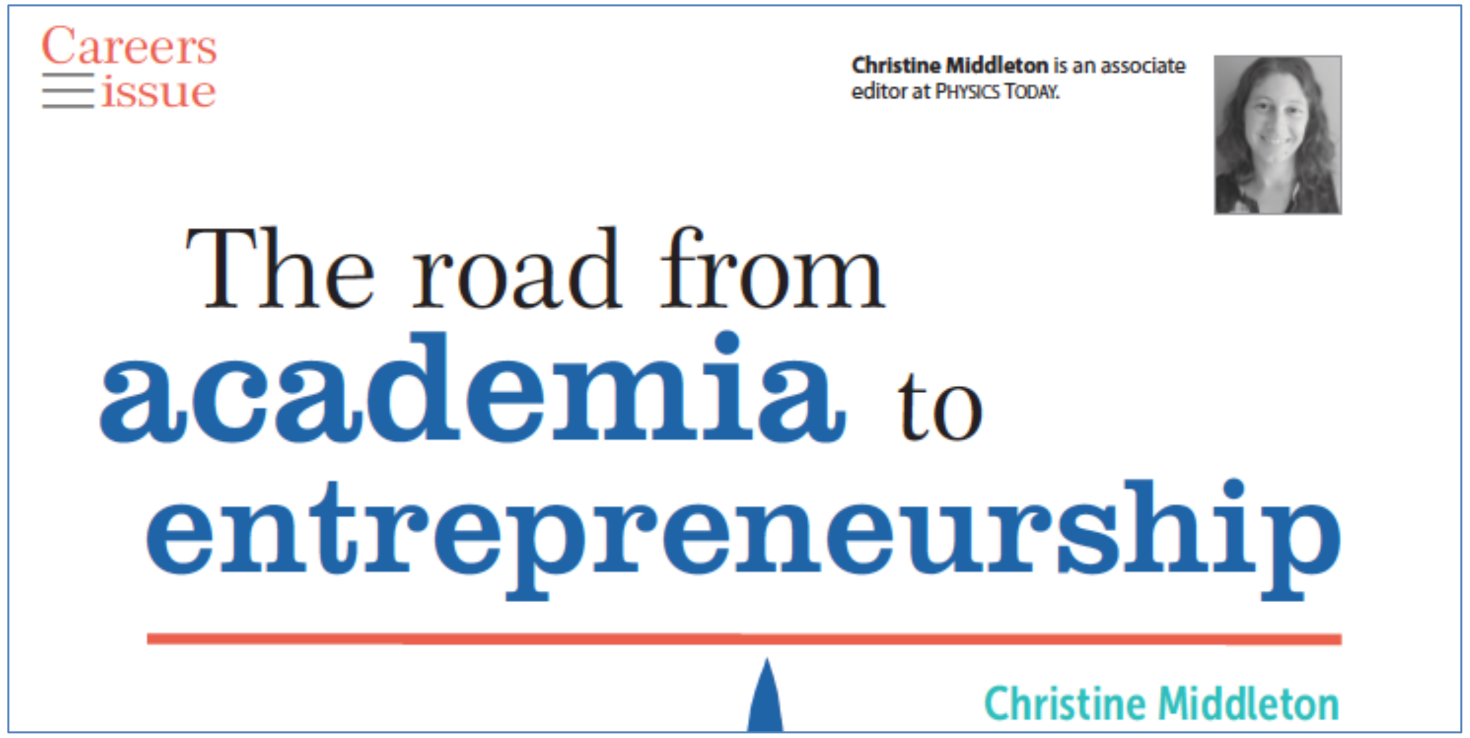


FIGURE 4. AN INNOVATION'S MATURITY can be characterized by its technology readiness level (TRL). Research at low TRLs (1–3) is typically performed at universities and funded by grants from foundations and the federal government. Work on technologies at high TRLs (7–9) is often funded by corporations. Startups can help bridge the gap between those development levels.



Careers issue

Christine Middleton is an associate editor at PHYSICS TODAY.

The road from **academia** to **entrepreneurship**

Christine Middleton

Physics Today, Oct 2021

BIRAC TRL Scale

- Website: https://www.birac.nic.in/desc_new.php?id=443
- Scales:

-- Drugs (including Drug Delivery)
-- Vaccines
-- Biosimilars
-- Regenerative Medicine
-- Medical Devices and Diagnosis
-- Artificial Intelligence, Big Data Analysis, IoT's, Software Development & Bioinformatics
-- Industrial Biotechnology (including secondary agriculture)
-- Agriculture
-- Aqua Culture and Fisheries
-- Veterinary

Example: De-risking Rapid RT-PCR

- POP: Can the RT-PCR be done in 30 min?
- Reliability of data: R&R
- **POC: S&S**
- Certification: Do you have third party test data? Ex IEC.
- **POV: Does it give quicker AND low false negatives compared to rapid antigen and conventional RT-PCR?**
- FTO: Does SOP/ method/ tools not infringe another patent? If it does, what is a work around?
- Own patent: Does data illustrate novelty and non-obviousness?
- IP coverage: Does it block competitors? Is there data for adequate variations?
- For KOLs: Is the data suitable and high quality for a peer reviewed publication?
- For clinical PI: Is the data convincing and credible? Was it done with credible methods and partners?
- For CDSCO submission: Is it safe? Does it do what it claims (efficacy)? Is data generated after test license? Is data from approved/ NABL labs? Is clinical study design approved? Is the population chosen well? Is the statistics okay?

Status of IP

- Provisional → Complete → Grant
- Age
- Strength of claims
    - Type of claim
    - Patentability; ISR
- Wide scope of claims
- Geographical coverage
- Oppositions
- Citations by others

What KOLs/experts have to say

KOL Opinion

Some things that KOL can comment on:

- Is the need/ problem being solved genuine and undisputed?
- How big/ pressing is the need?
- What are the alternative available today? What are the issues?
- Will the proposed solution solve the problem?
- What data would users/ buyers want to see to convince them?
- What should be the price point?
- How does the value chain work? What are the channels?
- Who might be interested in licensing?
- etc

Thinking through path ahead and strategy

Decision framework

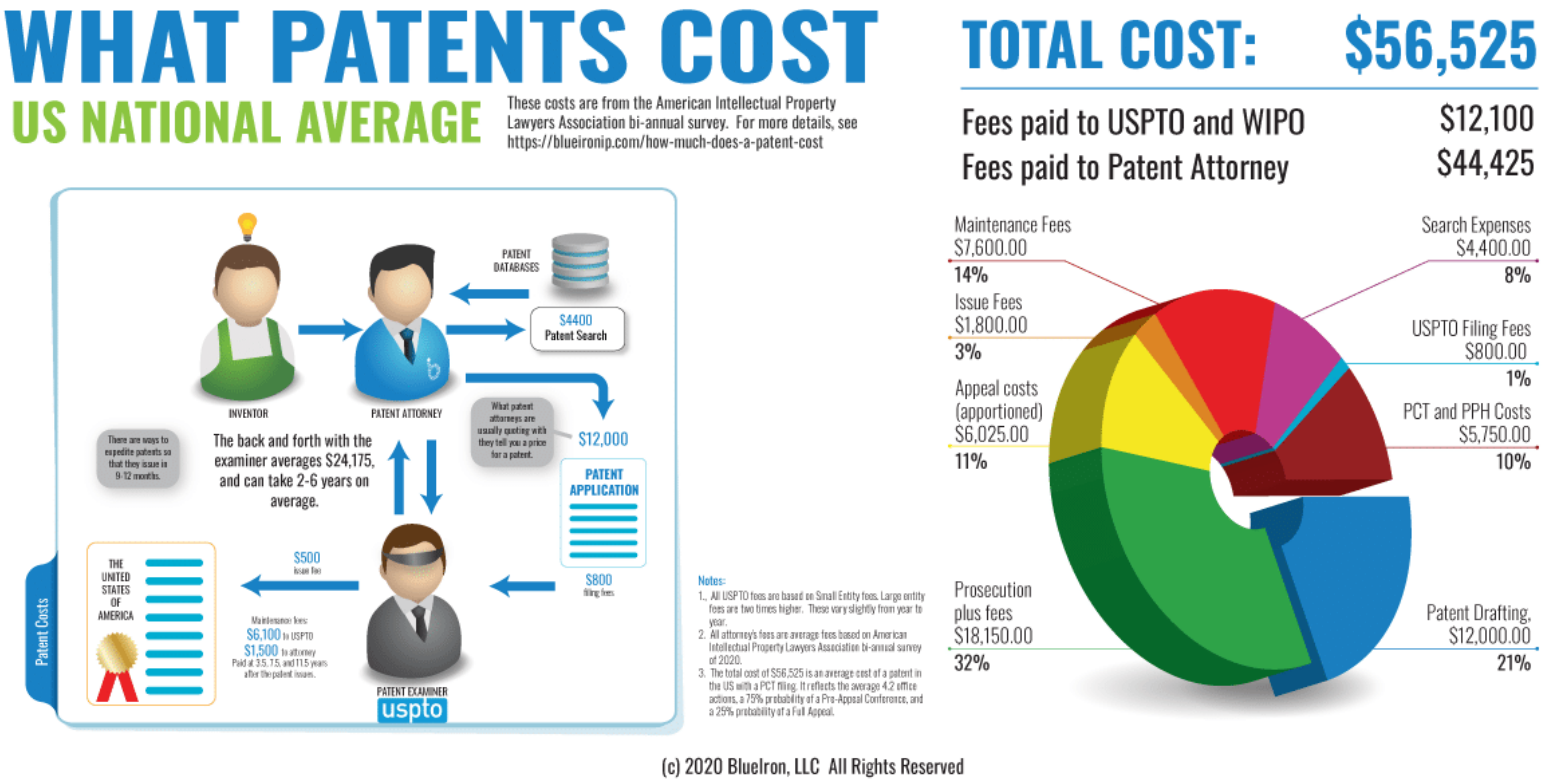
- What is the potential benefit?
  - Keep doors open; hold some cards to influence tech journey ("create options" for yourself, organization, country)
  - Attract resources/ funders/ investors for further development
  - Attract licensors/ assignees *(sometimes this is overemphasized in academia!)*
  - Attract development/ co-development projects
  - Have a voice on the table
  - Exclude others
  - Credit/ recognition
  - Indicator of inventive potential

- What is the potential cost and risks?
  - Funds for patent protection
  - Funds for advancing the technology
  - Time
  - Law suits

IP COSTS

- Drafting, filing, prosecution services/ IP attorney cost
- Statutory fees for filing, examination etc
- Others like translation costs
- Maintenance fees

- Note: There is no such thing as an "international patent". You have to protect individually in each region/ country
- Note: Applicant can file directly on their own. But if they use the help of attorneys/ agents, they usually need attorneys/ agents from that region/ country.



https://blueironip.com/average-patent-cost/

Final examples

Exercise: CNT Flow sensors

Carbon Nanotube Flow Sensors

Shankar Ghosh,[1] A. K. Sood,[1*] N. Kumar[2]

We report that the flow of a liquid on single-walled carbon nanotube bundles induces a voltage in the sample along the direction of the flow. The voltage that was produced fit a logarithmic velocity dependence over nearly six decades of velocity. The magnitude of the voltage depended sensitively on the ionic conductivity and on the polar nature of the liquid. Our measurements suggest that the dominant mechanism responsible for this highly nonlinear response involves a direct forcing of the free charge carriers in the nanotubes by the fluctuating Coulombic field of the liquid flowing past the nanotubes. We propose an explanation based on pulsating asymmetric ratchets. Our work highlights the device potential for nanotubes as sensitive flow sensors and for energy conversion.

Carbon Nanotube Flow Sensors

SHANKAR GHOSH, A. K. SOOD, AND N. KUMAR

SCIENCE
16 Jan 2003
Vol 299, Issue 5609
pp. 1042-1044

DOI: 10.1126/science.1079080

http://repository.ias.ac.in/50270/1/83_aut.pdf

Exercise: CRISPR

Abstract

Clustered regularly interspaced short palindromic repeats (CRISPR)/CRISPR-associated (Cas) systems provide bacteria and archaea with adaptive immunity against viruses and plasmids by using CRISPR RNAs (crRNAs) to guide the silencing of invading nucleic acids. We show here that in a subset of these systems, the mature crRNA that is base-paired to trans-activating crRNA (tracrRNA) forms a two-RNA structure that directs the CRISPR-associated protein Cas9 to introduce double-stranded (ds) breaks in target DNA. At sites complementary to the crRNA-guide sequence, the Cas9 HNH nuclease domain cleaves the complementary strand, whereas the Cas9 RuvC-like domain cleaves the noncomplementary strand. The dual-tracrRNA:crRNA, when engineered as a single RNA chimera, also directs sequence-specific Cas9 dsDNA cleavage. Our study reveals a family of endonucleases that use dual-RNAs for site-specific DNA cleavage and highlights the potential to exploit the system for RNA-programmable genome editing.

https://www.science.org/doi/10.1126/science.1225829

Exercise: CRISPR

VENTURE CENTER

Gene Editing Business Development Deals

Date/s	Companies	Agreement Details	# of Indications	Type	Upfront	Milestones
2021	AbbVie - Caribou	Discover and develop allogeneic CAR-T cell therapies using Caribou's Cas12a CRISPR hybrid chRDNA	4	Allo-CAR T	$40M	$300M
2021	Apellis - Beam	Discover novel therapies for complement-driven diseases using base editing	6	C3, Eye, Liver, Brain	$75M	u/d
2022	Bayer - Mammoth	Discover and develop in vivo CRISPR-based gene editing therapies	5	Liver-targeted	$40M	$1B
2021	Biogen - Scribe	Discover and develop CRISPR-based genetic medicines for neurological diseases	2	ALS, Neuro	$15M	$400M
2015, 2019	BMS - Editas	Develop and commercialize autologous and allogeneic T-cell therapies for cancer and autoimmune diseases	-	Alpha-Beta T cells	$25M + $70M	$22M
Jul-05	CRISPR - ViaCyte	Discovery, development, commercialization of gene-edited stem cell therapies for diabetes	1	diabetes	$15M	$10M
2021	Epsilen Bio - Chroma Medicine	Chroma acquires Epsilen Bio for epigenetic editing	-	-	u/d	N/A
2020	LifeEDIT - ElevateBio	ElevateBio acquires LifeEDIT for its next-generation gene-editing platform	-	-	u/d	N/A
2022	Pfizer - Beam	Discover and develop in vivo base-editing therapies	3	Liver, muscle, CNS	$300M	$1.05B
2021	Moderna - Metagenomi	Discover and develop next-generation in vivo gene-editing therapeutics	u/d	u/d	u/d	u/d
2021	Nkarta - CRISPR	Develop and commercialize gene-edited cell therapies for cancer	7	CD70 tumor antigen	u/d	u/d
2015 - 2019	Novartis - Intellia	Discover and develop CRISPR-based therapies using CAR Ts and HSCs	u/d	eye disorders	$6M + $10M	u/d
2016, 2020	Regeneron - Intellia	Discover and develop in vivo and ex-vivo CRISPR-based therapies for up to 10 targets including hemophilia A and B	15	Hemophilia A and B	$75M + $70M	$50M
2022	Rewrite - Intellia	Intellia acquired Rewrite to obtain its proprietary DNA writing platform	-	-	$200M	N/A
2021	Sana - Beam	Sana licenses Beam's CRISPR Cas12b gene-editing technology to enable engineered cell programs	u/d	Cancer, diabetes, cardio	$50M	u/d
2018, 2021	Vertex - Arbor Bio	Develop ex vivo cell therapies using Arbor's CRISPR gene-editing technology	u/d	T1 diabetes, SCD, BT	$30M	$1.2B
2015, 2019, 2021	Vertex - CRISPR	Discover and develop CRISPR-based therapies with amendment toward manufacturing and commercialization of CTX001 in SCD and BT; DMD, DM1	4	SCD, BT, DMD, DM1	$105M + $171M + $900M	$200M
2015, 2022	Vertex – Exonics Therapeutics	Vertex acquires Exonics Therapeutics to enhance its gene-editing capabilities for DMD and DM1	2	DMD, DM1	$254M	Up to $1B
2021	Vertex - Mammoth	Discovery and develop in vivo gene-editing therapies	2	u/d	$41M	$650M
2021	Verve - Beam	Discover and develop gene-editing therapies for heart disease	2	HeFH, HoFH	u/d	u/d

Source: Company reports; William Blair Equity Research

	Company	Country	Plant
1.	The Broad Institute	USA	Plants
2.	Pioneer Hi-bred Int'l	USA	Plants
3.	Corteva Agriscience	USA	Plants
4.	Syngenta	USA	Plants
5.	Monsanto	USA	Corn
6.	Benson Hill Seeds, Inc.	USA	Soybean
7.	Indigo, Ag. Inc.	USA	Seeds, Soybean
8.	Cellectis	France	Potato
9.	China Agricultural University	China	Plant
10.	Limagrain Cereal Seeds LLC	USA	Wheat
11.	Sakata Seeds Americas Inc.	USA	Tomato, Poblano Pepper
12.	KWS SAAT SE + Co KGaA	Germany/USA	Plants
13.	Pairwise Plant Services Inc.	USA	Plants, Consumer Crops
14.	Toolgen Inc.	USA	Potato
15.	Caribou Biosciences	USA	Plant
16.	Canbreed Ltd	Israel/USA	Cannabis
17.	Nanjing Agricultural University	China	Plants
18.	Arista Cereal Technologies	Australia	Wheat
19.	Agrisoma Bioscience, Inc.	Canada	Brassica Plant
20.	Golden West Research	Bulgaria	Cotton
21.	Ingari Agriculture	USA	Plant
22.	King Abdullah University	Saudi Arabia	Tobacco
23.	Nunhems B.V.	Netherlands	Cucumber, Carrot, Watermelon,
24.	Chinese Academy of Sciences	China	Plants
25.	Central Valley Seeds, Inc.	USA	Lettuce
26.	Tropic Biosciences, Ltd	UK	Banana
27.	Cibus LLC	USA	Plant

https://www.fdli.org/2021/11/the-future-of-food-crispr-edited-agriculture/

TechEx.in

Tech Transfer Hub at Venture Center
Supported by NBM - BIRAC

THANK YOU