



ambiom

Company introduction

ambiom – more than an advice



Photo Credits: Martin Katler
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Life science boutique advisory

ambiom s.r.o. (LLC)
incorporated in Bratislava,
Slovakia in November 2021.
Focus on commercial
services in life sciences:

- Business development
- Market access
- Technology transfer

About me

10 years of international
experience in consulting and
commercial roles in life
sciences of which most has
been spent in diagnostic and
early-stage pharmaceutical
companies.

Contributed to the reforms of
drug and medical device
reimbursement policy in
Slovakia.

B.Sc Molecular Biology
M.Sc Bioentrepreneurship /
Life Science Business
Administration

Services

Service line	Services
Business development services	Deal origination and arrangement Product & service strategy In- and Out-Licensing (incl. Valuation)
Market access services	Value dossier development Regulatory affairs Communication with authorities
Technology transfer services	Funding identification and sourcing Spin-off establishment Commercial technology assessment (FTO, patent landscape...)



Data-driven approach

We have built internal, and integrated external comprehensive scientific and commercial databases that help us with guiding our recommendations and in turn, your decisions.

Geographical and cultural expertise

We have an overview of local drug, medical device and other relevant regulation and speak the formal and informal language of Austria, Slovakia, Czech Republic and Ukraine. We know the people, the market and know how to navigate it.

Everything on 1 invoice

**Whenever possible, for fixed-term projects
and campaigns, we will budget for and bill
you only 1 invoice.**

No hidden fees.



Technology expertise

With a deep technology expertise in pharma, medtech, diagnostics as well as non-regulated products we can rapidly and efficiently deep-dive in various industry verticals.

People



UNIVERSITY OF AMSTERDAM

Lonza



UNIVERSITY OF
BATH



AIT
AUSTRIAN INSTITUTE
OF TECHNOLOGY
TOMORROW TODAY

Our engagement teams are built in a matrix organization with experienced people within ambiom and the respective experienced subcontractors. All of our staff has practical experience from policy, operational commercial roles in life sciences or academia.

Subcontractors



UNIVERSITY OF AMSTERDAM

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Without exception, our subcontractors have both academic and commercial background in life sciences with direct link to one of our service lines. The group includes PhDs in Neurobiology, Medical Doctors, Pharmacists; mid-career professionals as well as industry veterans from Europe and beyond.

Some of our current and former clients



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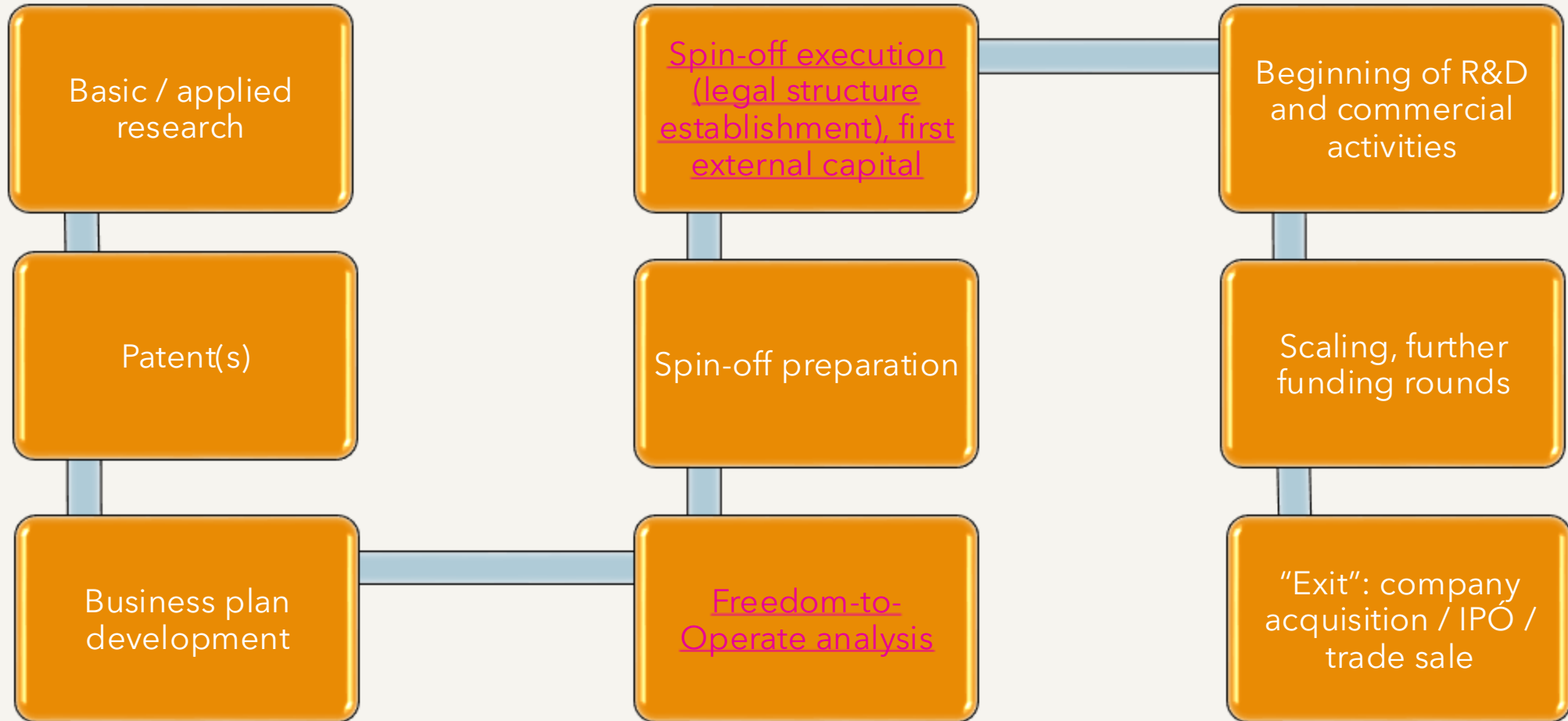
Academic spin-offs – best practices

ambiom – more than an advice

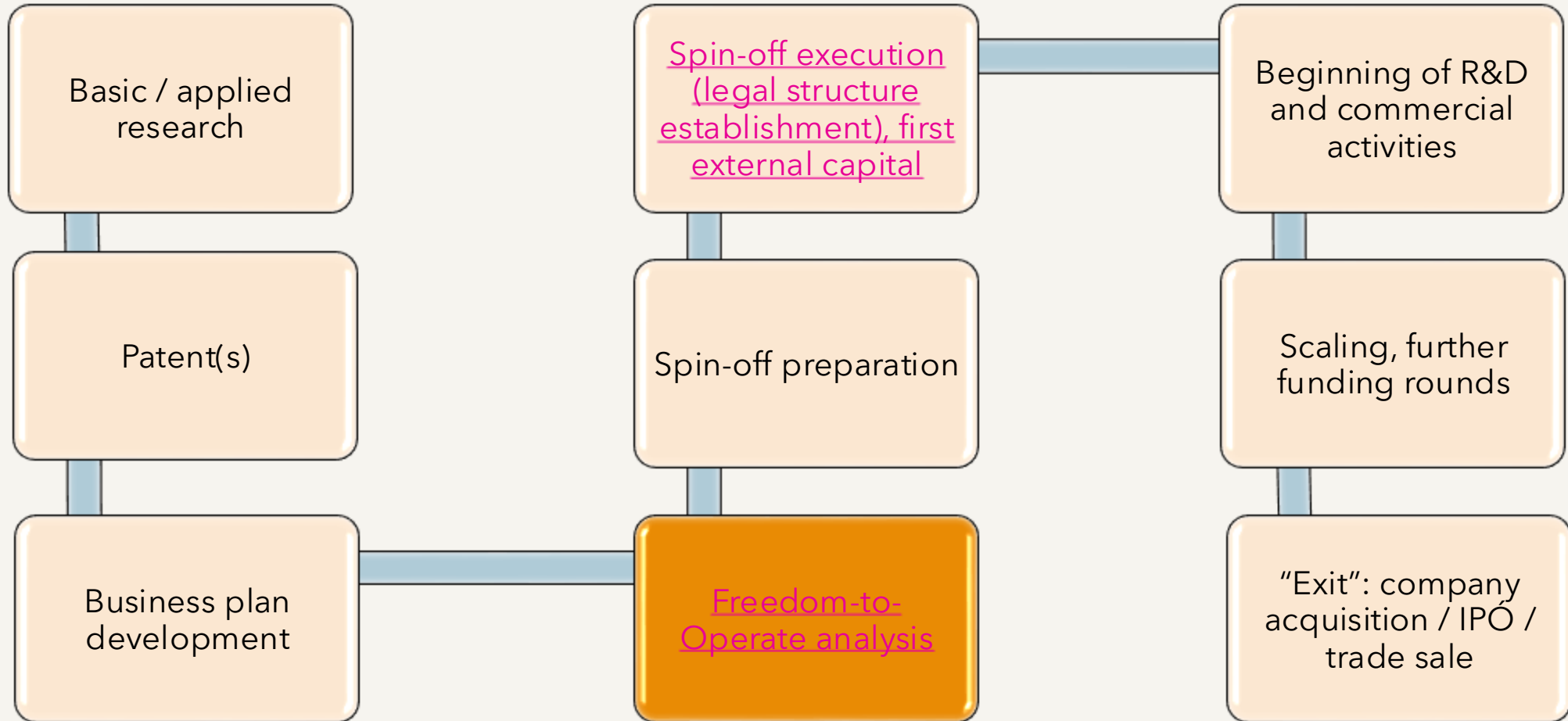
Academic spin-offs

- Spinning off = the process of commercialization of intellectual property outside of the mother institution by creating a company with a clear goal on how to monetize it.
- Worldwide the most active countries are China, US, Europe is generally lagging behind with a few exceptions (ETH Zurich, Oxford, Cambridge, Imperial College, Karolinska, some German institutes...).
- There is no unified pathway, but there are events we see happening over and over again that can be avoided, and on the other hand, actions and tasks that are generally ubiquitous.

Typical journey of a spin-off



Can't you just skip Freedom-to-Operate analysis?



Freedom-to-Operate – common misconceptions

- „Prior art has been checked during the patent application and if there were infringements my patent would not get approved, therefore I have FTO.“
- „If I have a granted patent I have an FTO.“
- „If I identify a potential obstacle during the FTO analysis, I have to close the business, there is no way of getting around that.“



Freedom-to-Operate

- Having a priority filing, PCT application or even successful national phases for a patent does not automatically grant you Freedom-to-Operate (FTO).
- Patent only provides you with a protection from others. Typically FTO main phases are as follows:

1. Primary qualitative interview research; interview the scientists or engineers in the company about the discovery. Your goal is to understand the scope of the science, the subject matter, therapeutic areas, and the specific market, among other factors.

2. Search strategy development; designing a search strategy for patents your invention might infringe on. Your goal is to find keywords that will help you find technology in the claims section of patent applications.

3. Review; reviewing the patents and looking at individual claims. Identify barriers to entry, or patents and technology that are most likely to block your pursuit of an intellectual property patent. "Discard" results that aren't relevant and keep the subset of patents that could present a problem.

4. Identify solutions; identifying solutions to specific issues. For example, you can look at the patent status, potential expiration, and/or research, and prepare an invalidity opinion.



Freedom-to-Operate – what to do?

- What can you do if your FTO identifies a potential infringement:
- **Acquisition or Licensing:** Purchasing the patent or obtaining a license involves securing authorization from the patent holder to use the technology within specified parameters. While this might entail royalties or lump-sum payments, it streamlines the path for product commercialization.
- **Cross-Licensing:** Companies can exchange licenses to use each other's patents, contingent on the mutually beneficial patent portfolios.
- **Inventing Around:** The company might innovate to circumvent patent infringement. This involves altering processes or products to achieve similar outcomes without violating existing patents.
- **Patent Pools:** Firms dealing with related technologies can aggregate patents in a pool to simplify patent rights management. A well-known example from the life science industry is e.g. the patent pool for HIV research.
- **Protective Patents:** If the FTO analysis indicates no barriers and a technology is patentable, seeking patent protection can enhance freedom to operate, rather than relying on trade secrets.



Freedom-to-Operate

10x Genomics Wins Another Patent Infringement Case Against NanoString Technologies



NEWS PROVIDED BY
10x Genomics, Inc →
17 Nov, 2023, 17:22 ET

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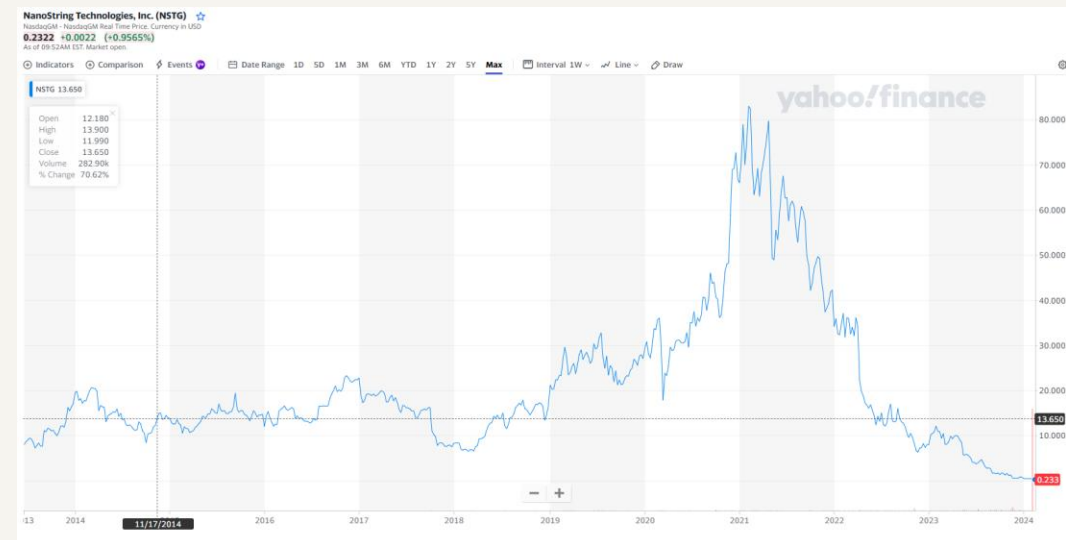
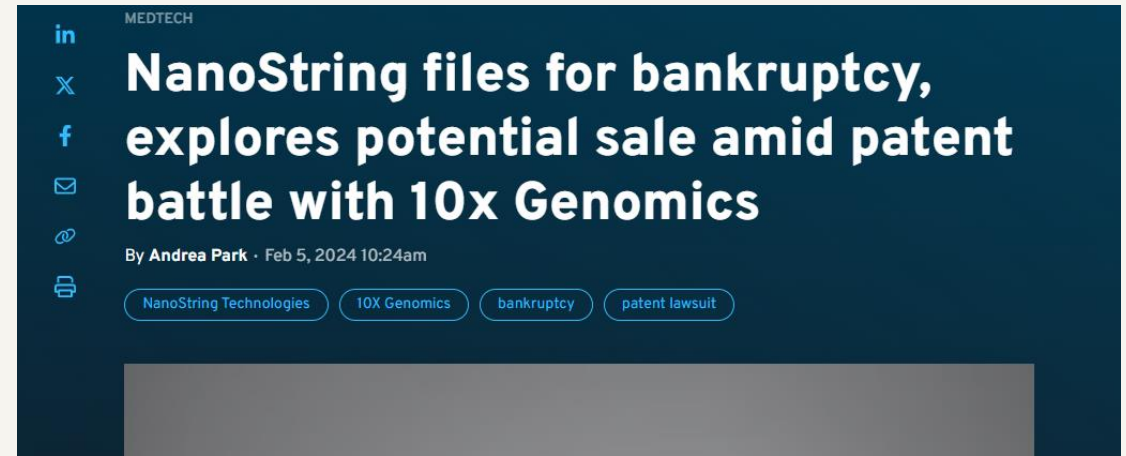


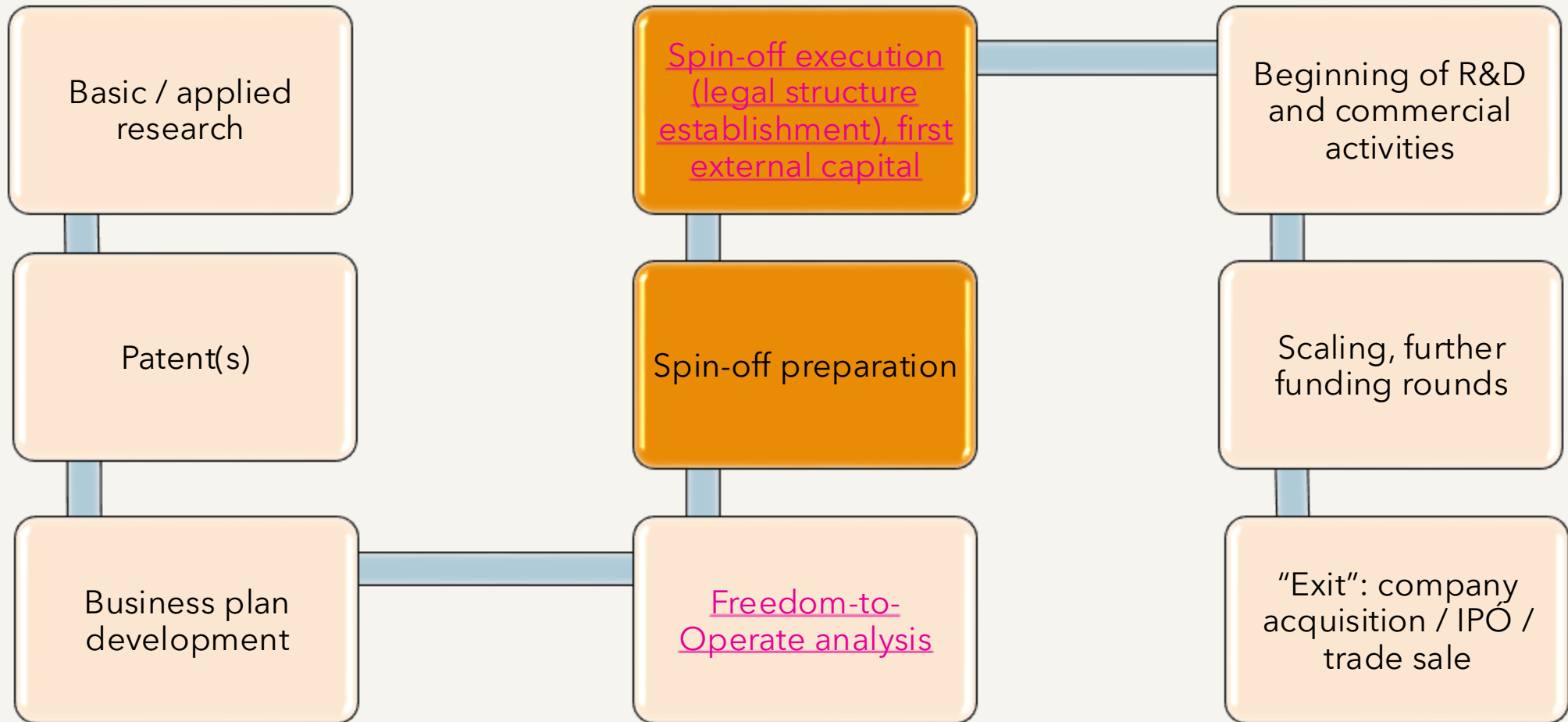
Jury Awards 10x Genomics Over \$31 Million in Damages and Finds All Seven Asserted Patents Valid and Willfully Infringed by NanoString

GeoMx Decision is Third Ruling Against NanoString, Showing Serial Infringement of 10x Patents

PLEASANTON, Calif., Nov. 17, 2023 /PRNewswire/ -- **10x Genomics, Inc.** (Nasdaq: **TXG**), a leader in single cell and spatial biology, announced today that a jury in the U.S. District Court for the District of Delaware has reached a unanimous verdict in favor of 10x Genomics in the patent infringement suit 10x filed against the GeoMx products sold by NanoString Technologies, Inc. (Nasdaq: **NSTG**). In awarding over \$31 million in damages, the jury found that NanoString's GeoMx Digital Spatial Profiler and associated instruments, reagents and services for RNA and protein detection willfully infringe all seven asserted patents owned by Prognosys and exclusively licensed to 10x Genomics.

The jury awarded over \$31 million in damages for sales of the infringing GeoMx products from May 6, 2021 through October 13, 2023. In post-trial proceedings, 10x intends to seek (a) ongoing royalties for NanoString's willful infringement by sales of the GeoMx products after October 13, 2023; (b) treble damages and attorney's fees for NanoString's willful

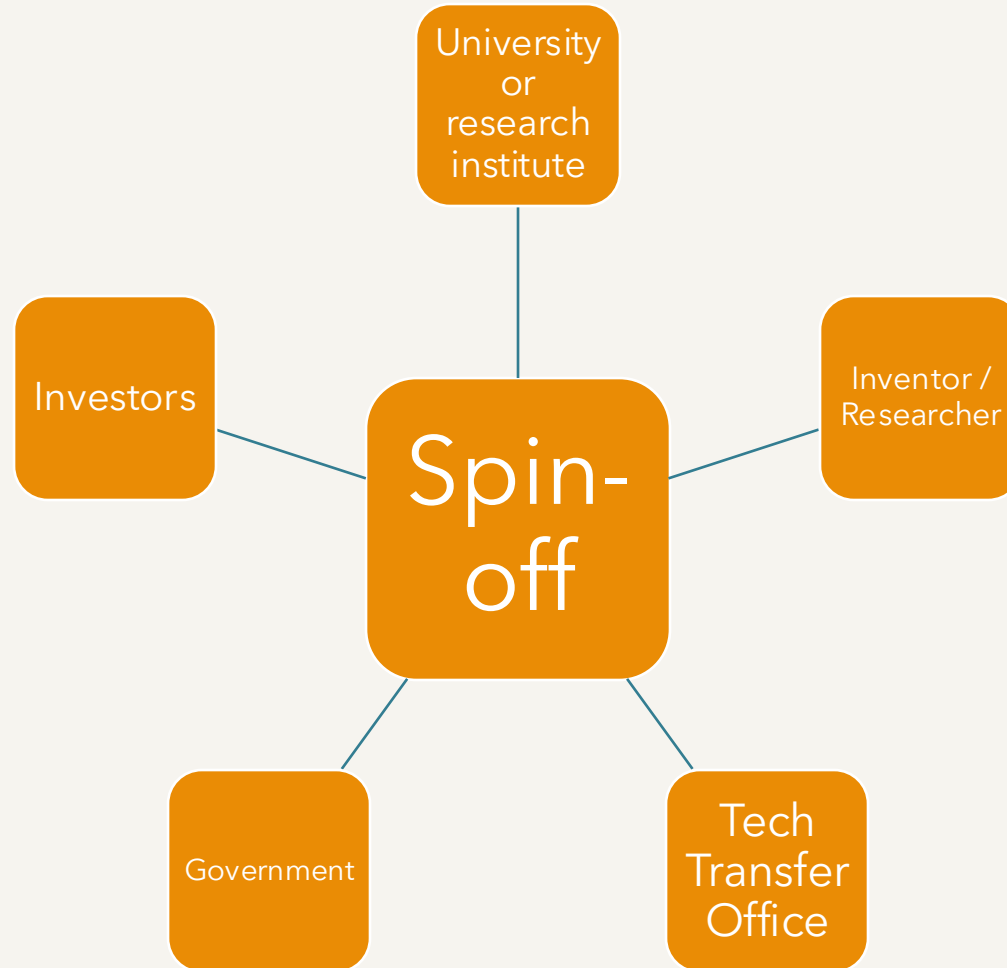




Spin-off preparation

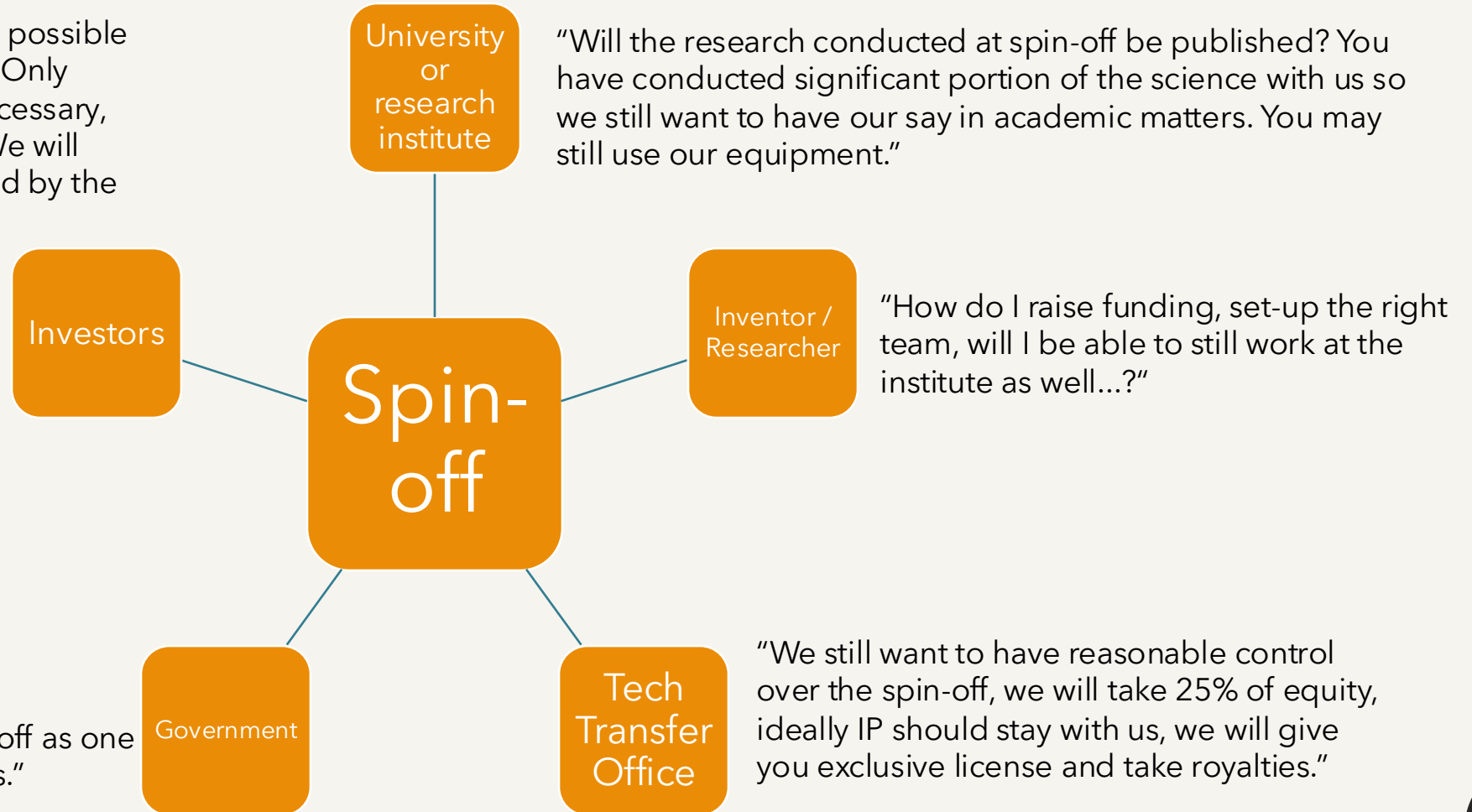
- **Stakeholders:** all of them with different interests.
- **Legal structure of the spin-off:** is there only one option of an limited liability company, which one could work best for you, which one could work best for your employees, which one could work best for the investors?
- **Governmental incentives:** does your government subsidy the R&D, commercial, manufacturing operations? Employment in high-tech area? If so under what circumstances.
- **IP transfer:** license or sale? Under what conditions?
- **Team:** how to hire all the right people, overcome the „science-bias“?
- **External capital:** do you need it? If yes, which type and when?

Stakeholders



Stakeholders

"We need you to be as effective as possible and 100% invested in the spin-off. Only deal with academia as much as necessary, focus on building a strong team. We will also not invest until IP is fully owned by the spin-off."



Legal structure

- Can have a significant influence over your future possibilities of getting employees and investors on board.
- Is there a specific type of legal structure made for spin-offs?
- In Slovakia there is a limited liability company (s.r.o.) as well as simple stock company (jsa) which may require as little as €1 capital and is set-up specifically for the ease of running a spin-off and administering investments.
- In Austria, there is only one type of limited liability company (GmbH) which eventually requires €35,000 in capital.
- Will you be able to set-up ESOP?

Governmental incentives

- **Governmental incentives:** what help is government able to provide - look for the information on the websites of respective ministries or promotional agencies.
- **UAE:** "Dubai Free Zones": retain 100% ownership over the company, as opposed to the need for a native UAE "sponsor" typically entitled to 51% of the ownership outside the free zones. You can be exempt from the corporate, personal, gift, import and export taxes, retain the full profits.
- **Austria:** As part of the Austrian government's life sciences strategy, there are significant tax reductions on 14% of the R&D expenditures, corporate, as well as on individual taxes.
- **Czech Republic:** Changes, which came into effect in 2022, allow the companies more access to direct financial support for strategic investment actions, given that the investors invest a large sum of money towards the equipment used for R&D purposes and that they create 250 new employment opportunities.

IP transfer

- How will be the needed know-how and IP formally transferred to the spin-off?
- Exclusive worldwide license: Often suggested by TTOs, can be destructive for the spin-off chances.
- Sale of the IP to the spin-off often only viable option. TTO needs to understand that the success of the spin-off depends on the smooth transfer of the underlying intellectual property.
- TTO may require equity stake in the spin-off – this can be anywhere from 1% to 60%. This may again be detrimental to the success of the spin-off and its ability to raise funding.
- Ideally, an experienced life science patent attorney should oversee the transaction.
- **Sweden:** Researchers automatically own the IP themselves rather than the mother institution. This makes the process much easier.

Team

- Life science spin-offs are typically initially heavy on the R&D side (there is a “science bias”) but this is not sustainable long term.
- DO NOT simply employ PhDs and post-docs from your group at university because you know them, do a proper hiring process for specific roles.
- If you get external investors, they will require the spin-off team to be 100% committed to the spin-off.
- Overlap in understanding all aspects of the spin-off between founding team is from our experience a necessity. Business people should be able to explain basic science, scientists should understand basic business concepts.



External capital

- Only raise money if absolutely necessary for your project - might be unavoidable for pharmaceutical spin-offs but potentially feasible to „bootstrap“ for digital health applications.
- In exchange of (private) capital you give up control of your company.
- In any case, create a side revenue stream as soon as possible (fee4service, bioanalytical services, small contract research...).

External capital

Grants

- Applied research funding agencies
- Entrepreneurship funding agencies
- European Union grants

Venture Capital

- Traditional Venture Capital
- Corporate Venture Capital

Business Angels

- With industry experience
- Without industry experience
- Angel syndicates

Other External Capital

- Strategic alliances
- Accelerators
- Family offices
- Friends&Family
- Crowdfunding
- Patient organizations

Q&A

Visit: www.ambiom.com or reach out to us: info@ambiom.com