Una subvención de educación médica independiente respaldada en colaboración por la Sociedad Americana de Terapia Génica y Celular y Pfizer.

Terapia génica

para enfermedades raras

Pontificia Universidad JAVERIANA Bogotá

American Society of Gene + Cell Therapy

Pfizer

IEIM

Propiedad intelectual en el área de la terapia génica

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00:00:04.625 --> 00:00:07.525

So welcome to this lecture on patenting gene

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00:00:07.625 --> 00:00:08.765

and cell therapies.

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00:00:08.905 --> 00:00:10.365

My name is Joanna Applequist,

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00:00:10.665 --> 00:00:13.165

and I will take you through

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00:00:13.255 --> 00:00:15.725

basic knowledge about intellectual property

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00:00:15.825 --> 00:00:18.005

and the challenges

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6
00:00:18.065 --> 00:00:21.125
and opportunities in protecting gene

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00:00:21.185 --> 00:00:22.445
and cell therapies.

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00:00:24.305 --> 00:00:26.805
So I come from a company called AWA,

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00:00:26.865 --> 00:00:30.645
and we're a global company with presence in Europe as well

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00:00:30.645 --> 00:00:34.165
as in Asia and in other countries.

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00:00:34.185 --> 00:00:37.485
We work with a very well established group of partners,

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00:00:37.495 --> 00:00:39.325
local attorneys all over the world.

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00:00:39.985 --> 00:00:43.845
And we are about 400 employees at AWA

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00:00:44.025 --> 00:00:48.445
and 230 of us are consultants within the IP field,

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00:00:48.505 --> 00:00:51.285
we are patent attorneys, we're attorneys at law,

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00:00:51.285 --> 00:00:52.605
and also other specialists

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00:00:53.545 --> 00:00:57.965
and together we represent over 4,300 different

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00:00:57.965 --> 00:00:59.365
clients all over the world.

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00:01:00.105 --> 00:01:02.445

And we have a very strong life science team,

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00:01:02.545 --> 00:01:05.645
the strongest one in Scandinavia with over 40 attorneys

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00:01:06.185 --> 00:01:08.125
across multiple specialized fields.

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00:01:09.105 --> 00:01:11.965
And we work in technology ranging from cell

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00:01:11.965 --> 00:01:14.685
and gene therapies, small molecules, biologics

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00:01:14.845 --> 00:01:17.725
and formulations to bio technological invention,

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00:01:18.075 --> 00:01:22.045
diagnostics, digital healthcare, med tech, and AI.

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00:01:23.065 --> 00:01:26.605
And we support large players such

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00:01:26.905 --> 00:01:31.805
as large multinational companies, as well

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00:01:31.805 --> 00:01:34.285
as small and medium sized enterprises, as well

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00:01:34.285 --> 00:01:35.445
as startup companies.

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00:01:36.585 --> 00:01:40.565
So, who am I? My name is Joanna Applequist, and I'm a partner

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00:01:40.745 --> 00:01:42.685
and european patent attorney at AWA.

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00:01:43.315 --> 00:01:46.205
I've been working in the IP field since 2011,

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00:01:46.305 --> 00:01:48.365
and prior to that I defended my doctoral thesis

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00:01:48.945 --> 00:01:52.445
in Salon Molecular Biology at the Karolinska Institutet,

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00:01:52.575 --> 00:01:55.325
where I also did a postdoctoral fellowship.

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00:01:56.325 --> 00:01:57.845
I specialize in the field of cell

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00:01:57.845 --> 00:02:00.805
and molecular biology, including cell and gene therapies,

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00:02:01.265 --> 00:02:04.925
and I work with pharma inventions, biologics, vaccines,

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00:02:04.945 --> 00:02:07.885
and also bio technological applications to mention a few.

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00:02:08.785 --> 00:02:11.605

And most importantly, having an academic background,

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00:02:12.165 --> 00:02:15.085

I very much enjoy working closely with scientists

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00:02:15.385 --> 00:02:16.885

and inventors.

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00:02:17.505 --> 00:02:19.685

Please feel free to reach out after this lecture.

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00:02:20.135 --> 00:02:22.005

There is no question that is too small

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00:02:22.065 --> 00:02:23.845

and I would be most happy to hear from you.

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00:02:24.825 --> 00:02:27.725

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So today we are gonna go through,

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00:02:28.265 --> 00:02:29.845
these points.

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00:02:30.435 --> 00:02:32.405
This is a general introduction to patents,

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00:02:32.425 --> 00:02:35.605
and then introduction to life science related inventions.

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00:02:36.255 --> 00:02:38.285
We're gonna dive a little deeper into gene

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00:02:38.285 --> 00:02:41.365
and cell therapy patenting, and we're gonna discuss second

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00:02:41.425 --> 00:02:42.805
and further medical uses.

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00:02:43.185 --> 00:02:46.245
And lastly, we'll consider IP as a business tool.

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00:02:47.385 --> 00:02:50.765
So with further a no further ado, let's get started

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00:02:51.705 --> 00:02:54.325
with the general introduction to patents.

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00:02:57.825 --> 00:02:59.605
So patents, what is a patent?

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00:02:59.875 --> 00:03:01.685
Well, patents are timely limited

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00:03:02.325 --> 00:03:03.925
national rights of prohibition.

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00:03:04.585 --> 00:03:05.925
So what does that really mean?

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00:03:06.195 --> 00:03:08.085

Well, the legal rights that are conferred

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00:03:08.105 --> 00:03:11.205

by a patent on negative rights does having a patent

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00:03:11.225 --> 00:03:12.885

for your invention gives you the right

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00:03:12.885 --> 00:03:14.645

to stop others from using your invention.

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00:03:15.545 --> 00:03:17.645

It does not automatically mean

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00:03:17.685 --> 00:03:20.845

that you may yourself may use your invention in a commercial

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00:03:20.845 --> 00:03:24.165

setting as for example, there may be conflicting rights

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00:03:24.165 --> 00:03:26.245
that belong to others that will hinder you,

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00:03:27.225 --> 00:03:30.605
or there may be requirements within the regulatory field

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00:03:30.665 --> 00:03:32.605
for an regulatory approval or the like.

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00:03:33.645 --> 00:03:34.645
A patent may be valid

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00:03:34.705 --> 00:03:37.405
for 20 years from filing the patent application,

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00:03:38.405 --> 00:03:41.805
provided that annuities or so-called renewal fees are paid,

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00:03:43.185 --> 00:03:46.925

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and patents are the national, regional rights.

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00:03:47.155 --> 00:03:48.485
This means that a patent granted

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00:03:48.585 --> 00:03:50.925
for an invention may be different in different

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00:03:50.925 --> 00:03:55.205
jurisdictions, and it is the claims of the patents,

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00:03:55.585 --> 00:03:59.285
the laws of the patents that decide what

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00:03:59.845 --> 00:04:01.805
a patent prohibits others from doing.

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00:04:02.745 --> 00:04:05.245
And we will look a little closer at patent claims

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00:04:05.505 --> 00:04:06.565
and what they are.

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00:04:08.785 --> 00:04:11.085
But first, let's consider what inventions are.

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00:04:11.835 --> 00:04:16.645
Well, the European legal tradition says that

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00:04:17.475 --> 00:04:20.805
patents may be granted for any inventions in all fields

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00:04:20.825 --> 00:04:23.245
of technology, provided that the invention is new,

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00:04:23.875 --> 00:04:25.365
that they involve an inventive step

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00:04:25.745 --> 00:04:27.925
and are susceptible to industrial application.

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00:04:27.985 --> 00:04:29.325
And this is more

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00:04:29.345 --> 00:04:33.885
or less the same in other, in all other jurisdictions

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00:04:33.885 --> 00:04:37.085
around the world, although

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00:04:37.625 --> 00:04:39.365
it may be worded a little differently,

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00:04:39.625 --> 00:04:44.445
but this is the essence of patentability. In Europe,

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00:04:44.865 --> 00:04:47.885
the law also defines what is not patentable

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00:04:48.025 --> 00:04:52.405
and here is a graphic picture of tech of areas

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00:04:52.555 --> 00:04:55.965
that are not subject to patents in Europe.

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00:04:56.945 --> 00:05:01.365
So the European tradition, European legal tradition,

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00:05:01.435 --> 00:05:03.045
defines what inventions are not,

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00:05:03.065 --> 00:05:05.405
and they're not discoveries or theories

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00:05:05.465 --> 00:05:08.765
or mathematical methods are not aesthetic creations,

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00:05:09.585 --> 00:05:11.165
they're not schemes, rules

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00:05:11.225 --> 00:05:14.645

and methods for performing mental acts or playing games

101
00:05:14.705 --> 00:05:17.605
or doing business, not programs for computers

102
00:05:17.625 --> 00:05:19.205
or presentations or information.

103
00:05:19.865 --> 00:05:22.245
So if you come to think about it, defining

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00:05:22.355 --> 00:05:25.365
what inventions are not is sort of smart

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00:05:25.365 --> 00:05:29.445
because the law makers at the time

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00:05:29.445 --> 00:05:31.205
of writing the law could not imagine

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00:05:31.775 --> 00:05:33.365
where technology would take us

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00:05:33.605 --> 00:05:35.285
because technology's constantly evolving.

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00:05:35.945 --> 00:05:39.645
And I'll contrast this a little bit with the US law

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00:05:39.645 --> 00:05:42.525
because these are the two major two jurisdictions

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00:05:43.035 --> 00:05:47.085
that are of great importance in the world

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00:05:47.545 --> 00:05:52.205
and we work very much

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00:05:52.475 --> 00:05:56.405
with for the biotechnology market.

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00:05:57.425 --> 00:06:01.045

So the US law instead defines

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00:06:01.735 --> 00:06:04.285

patentable inventions in a positive manner

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00:06:04.385 --> 00:06:06.925

it says whoever invents or discovers new

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00:06:06.925 --> 00:06:10.045

and useful process machine manufacturer composition

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00:06:10.045 --> 00:06:11.845

of matter or any new

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00:06:11.865 --> 00:06:15.405

and useful improvement thereof may pertain a patent.

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00:06:24.425 --> 00:06:28.725

So patents are granted for inventions to inventors.

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00:06:29.385 --> 00:06:32.645

So an invention is a technical solution to a problem.

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00:06:32.865 --> 00:06:35.605

An invention may be a product, for example, a molecule,

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00:06:35.805 --> 00:06:37.245

a composition, or a cell line.

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00:06:37.625 --> 00:06:40.365

It may be a process or a method, for example, method

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00:06:40.385 --> 00:06:42.645

of production, or it may be a use.

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00:06:43.185 --> 00:06:46.605

And when an invention is born with it's conceptualized

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00:06:46.825 --> 00:06:49.445

and put into practice by an inventor,

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00:06:50.225 --> 00:06:53.885

the inventor automatically gets a right to a patent

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00:06:54.265 --> 00:06:55.285

for that invention.

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00:06:55.825 --> 00:06:57.125

And that means that everybody

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00:06:57.185 --> 00:07:00.005

who gets the same idea will also get the right to a patent.

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00:07:00.595 --> 00:07:04.445

However, it is the inventor, the inventor who is first

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00:07:04.465 --> 00:07:08.005

to file a patent application that will obtain the patent.

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00:07:09.345 --> 00:07:13.365
So is of course, always a hurry

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00:07:13.545 --> 00:07:16.085
to file a patent application if you consider

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00:07:16.115 --> 00:07:18.045
that there are others

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00:07:18.155 --> 00:07:21.365
that are competing within the same field of technology

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00:07:22.265 --> 00:07:25.565
and the right to patent, it may be assigned by law

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00:07:25.625 --> 00:07:28.925
by terms of employment transfer agreements and so on.

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00:07:29.665 --> 00:07:32.565
So it's not the inventor himself,

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00:07:32.665 --> 00:07:35.325

but an an applicant, a company that, for example,

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00:07:35.345 --> 00:07:36.605

the inventor is working for

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00:07:37.265 --> 00:07:41.045

or a academic institution that is applying for the patent.

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00:07:44.785 --> 00:07:49.285

So which patentability criteria then does my invention need

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00:07:49.285 --> 00:07:51.725

to fulfill in order for it to be patentable?

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00:07:52.515 --> 00:07:55.725

Well, like we said before, the invention has to be novel.

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00:07:56.385 --> 00:07:58.125

It has to exhibit inventive step,

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00:07:58.265 --> 00:08:01.525

and it has to be susceptible to industrial application.

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00:08:02.185 --> 00:08:03.805

So let's look at what this really means.

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00:08:04.935 --> 00:08:09.085

These criteria, a novelty of inventive step, have

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00:08:09.085 --> 00:08:11.085

to be fulfilled in relation to everything

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00:08:11.085 --> 00:08:13.445

that was publicly available on the day prior

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00:08:13.445 --> 00:08:14.965

to filing the patents application.

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00:08:15.625 --> 00:08:18.005

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So if you, for example, wish to publish your findings,

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00:08:18.145 --> 00:08:20.725
you may do so on the same day

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00:08:20.945 --> 00:08:23.565
as you file the patents application, but not the day before.

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00:08:23.795 --> 00:08:26.845
Because if you do publish it the day

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00:08:26.865 --> 00:08:30.285
before, then you've destroyed the patent's ability of your

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00:08:30.665 --> 00:08:31.725
invention.

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00:08:33.185 --> 00:08:36.765
Moreover, the invention has to be non-obvious

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00:08:36.785 --> 00:08:39.005
to a person skill in the art in order

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00:08:39.025 --> 00:08:40.565
to have inventive step.

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00:08:40.985 --> 00:08:43.245
So there has to be an inventive thought, there has

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00:08:43.245 --> 00:08:45.325
to be something extra smart about the invention.

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00:08:46.185 --> 00:08:47.725
And what does that really mean?

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00:08:48.065 --> 00:08:51.605
So we use this

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00:08:52.365 --> 00:08:55.485
fictitious person, a skilled person

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00:08:55.705 --> 00:08:58.525

who is somebody who's working in the field of technology

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00:08:59.345 --> 00:09:02.205

and they know,

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00:09:02.745 --> 00:09:04.805

they're aware of everything

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00:09:04.805 --> 00:09:08.085

that's publicly available within this field of technology,

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00:09:08.145 --> 00:09:11.925

but they have no creativity, no inventive thought.

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00:09:11.945 --> 00:09:14.685

So they can only do what the technology teaches

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00:09:14.865 --> 00:09:15.885

and prompts them to do.

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00:09:17.025 --> 00:09:21.685

So if there are teachings in technology for, that's say

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00:09:21.685 --> 00:09:25.605

that you, for example, need to combine two things

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00:09:26.665 --> 00:09:28.685

the skill person will do that.

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00:09:28.745 --> 00:09:32.245

He will not consider replacing thing two

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00:09:32.465 --> 00:09:33.845

for a different item

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00:09:34.355 --> 00:09:36.885

because that has not been taught about technology

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00:09:36.945 --> 00:09:39.325

and that might be the subject of the invention.

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00:09:40.745 --> 00:09:43.605
And invention has to be industrially applicable,

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00:09:43.605 --> 00:09:45.325
and that basically means that it has

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00:09:45.325 --> 00:09:47.005
to be useful in industrial setting.

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00:09:50.385 --> 00:09:53.005
So what did I mean by saying everything

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00:09:53.005 --> 00:09:54.285
that was publicly available?

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00:09:55.235 --> 00:09:56.845
Well, an invention is only novel if

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00:09:56.945 --> 00:10:00.645
it has it if it has not been described anywhere in the prior

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00:10:00.745 --> 00:10:05.165
art, and it has to be non obvious compared

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00:10:05.165 --> 00:10:07.525
to all well known in the prior art.

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00:10:08.225 --> 00:10:10.965
And forms of prior art are all different types

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00:10:10.985 --> 00:10:12.005
of publications

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00:10:12.185 --> 00:10:14.925
and it doesn't have mean only written publications

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00:10:14.945 --> 00:10:16.205
and written disclosures.

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00:10:16.985 --> 00:10:19.205

It is oral disclosures as well,

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00:10:19.345 --> 00:10:20.685

it is oral presentations,

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00:10:20.755 --> 00:10:25.205

this information over the internet, it is use prior use,

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00:10:25.375 --> 00:10:27.165

sales of items, etc.

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00:10:27.945 --> 00:10:31.645

And it's not really necessary that somebody has

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00:10:32.565 --> 00:10:36.845

actually accessed information for it to be destroying

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00:10:36.905 --> 00:10:37.965

our patentability

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00:10:38.075 --> 00:10:41.085
because if it could have been accessed,

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00:10:41.085 --> 00:10:42.965
then the information is considered

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00:10:42.965 --> 00:10:45.085
to be available according to the law.

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00:10:45.825 --> 00:10:47.525
And available also means

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00:10:47.525 --> 00:10:50.005
that there is no secrecy agreement in place

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00:10:50.045 --> 00:10:51.525
relating to that information.

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00:10:51.785 --> 00:10:56.645

So if you are engaging in

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00:10:57.065 --> 00:11:01.565
interactions with collaborators, investors

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00:11:01.825 --> 00:11:03.365
and so on, it's very important

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00:11:03.545 --> 00:11:07.565
to have non-disclosure agreements in place when you're

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00:11:07.565 --> 00:11:08.845
discussing your technology.

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00:11:11.425 --> 00:11:13.045
So I mentioned patent claims

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00:11:13.185 --> 00:11:15.565
and I thought we would spend a lot of time trying

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00:11:15.565 --> 00:11:17.565
to understand what patent claims are

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00:11:17.565 --> 00:11:20.365
because patent claims are very important.

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00:11:20.395 --> 00:11:23.405
They are the laws of the patent, they are what define

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00:11:23.675 --> 00:11:25.925
what the patent prohibits others from doing.

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00:11:27.025 --> 00:11:30.005
So what a patent protects is defined in the patent claims.

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00:11:31.385 --> 00:11:35.325
And this is why we

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00:11:35.325 --> 00:11:38.285
as patent attorneys spend a lot of time thinking

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00:11:38.385 --> 00:11:42.565

and working with the way we word patent claims.

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00:11:43.435 --> 00:11:45.365

It's a way of describing the technology

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00:11:46.025 --> 00:11:49.005

and making sure that the technology,

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00:11:49.005 --> 00:11:51.325

what we described in the patent claims is different

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00:11:51.435 --> 00:11:53.165

from the prior art.

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00:11:54.425 --> 00:11:58.125

And to add complexity to this,

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00:11:58.785 --> 00:12:01.325

it is the fact that that patent laws varies

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00:12:01.325 --> 00:12:02.845
between different jurisdictions.

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00:12:03.225 --> 00:12:06.925
And this affects on how an invention may be protected.

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00:12:07.745 --> 00:12:11.445
This means that the patent claims that relate

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00:12:11.465 --> 00:12:13.245
to the same invention have

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00:12:13.245 --> 00:12:16.165
to be worded differently in different countries taking into

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00:12:16.475 --> 00:12:19.005
account the specific of that country's laws

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00:12:20.225 --> 00:12:24.325

and then of course

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00:12:26.235 --> 00:12:29.645
patents when finally granted may also

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00:12:30.465 --> 00:12:32.085
be different in different countries

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00:12:32.085 --> 00:12:35.805
because the different authorities that

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00:12:37.075 --> 00:12:38.965
examine the patent applications,

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00:12:39.945 --> 00:12:42.325
so they have different laws

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00:12:42.515 --> 00:12:44.845
that they are examining them under. But also

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00:12:44.845 --> 00:12:47.325
because there is a part

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00:12:48.065 --> 00:12:50.965
and a component of subjectivity

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00:12:51.075 --> 00:12:53.725
because the patent examiner at the authority

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00:12:54.465 --> 00:12:56.125
is a human being, a person,

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00:12:56.625 --> 00:13:00.725
and they may be make different judgment calls.

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00:13:01.465 --> 00:13:05.925
So there are several reasons why different patent claims may

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00:13:05.925 --> 00:13:07.605
be granted in different jurisdictions.

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00:13:07.995 --> 00:13:10.525

Were both due to the differences in law

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00:13:10.525 --> 00:13:11.565

and those jurisdictions,

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00:13:11.565 --> 00:13:14.605

but also due to the subjective examination process.

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00:13:16.385 --> 00:13:21.205

So if we have an example of a patent claim, so generally

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00:13:24.185 --> 00:13:26.885

we, in patent claims, we use features

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00:13:27.465 --> 00:13:28.645

to describe the invention

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00:13:29.305 --> 00:13:31.965

and in principle, the two types of features:

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00:13:31.965 --> 00:13:35.965

these are structure features and functional features.

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00:13:36.025 --> 00:13:38.325

So structure features, they describe the appearance,

258

00:13:38.325 --> 00:13:40.005

the physical properties of the invention.

259

00:13:40.625 --> 00:13:44.125

If we are, for example, wanting to patent the cell line,

260

00:13:44.345 --> 00:13:47.285

it may be characterized by obstructions features such

261

00:13:47.285 --> 00:13:49.205

as the presence of a recombinant vector

262

00:13:49.275 --> 00:13:52.645

with a specific sequence or the expression

263
00:13:52.645 --> 00:13:54.965
or presence of a recombinant protein or receptor

264
00:13:54.985 --> 00:13:56.485
or biomarker or the like.

265
00:13:57.705 --> 00:13:59.245
On the other hand, functional features,

266
00:13:59.245 --> 00:14:01.085
they describe the functional properties

267
00:14:01.105 --> 00:14:03.565
and what an invention is capable of doing.

268
00:14:04.425 --> 00:14:08.445
So the application should include a description of

269

00:14:08.465 --> 00:14:11.325
how these functional features should be measured in order

270
00:14:11.465 --> 00:14:13.325
for the functional features to make sense

271
00:14:13.385 --> 00:14:14.525
and be reproducible.

272
00:14:15.425 --> 00:14:19.405
And these type of features, they are heavily relying on

273
00:14:20.805 --> 00:14:23.245
presence of data in the application

274
00:14:23.245 --> 00:14:25.085
with those features have been demonstrated.

275
00:14:25.465 --> 00:14:29.365
But for example a cell line may be characterized

276
00:14:29.505 --> 00:14:31.685
by a functional feature such as ability

277
00:14:31.825 --> 00:14:33.645
to induce immune response

278
00:14:33.785 --> 00:14:37.205
or ability to bind target, for example,

279
00:14:37.235 --> 00:14:38.525
with a specific affinity.

280
00:14:40.425 --> 00:14:43.805
So we're gonna look a little bit here at a claim

281
00:14:43.835 --> 00:14:47.845
that I have written on this slide.

282
00:14:47.915 --> 00:14:50.125
It's a claim relating to a cell

283
00:14:51.145 --> 00:14:53.885
and the cell is characterized by

284
00:14:54.565 --> 00:14:57.045
structure features in blue, relating to the presence

285
00:14:57.705 --> 00:15:01.765
of a CAR or CAR chimeric antigen receptor,

286
00:15:02.785 --> 00:15:04.405
and how what

287
00:15:04.405 --> 00:15:07.685
that receptor actually looks like in terms of structure

288
00:15:08.425 --> 00:15:12.045
and then in red is

289
00:15:12.345 --> 00:15:16.725

are functional features of the I domain of

290
00:15:16.875 --> 00:15:21.765
that receptor and stating that this domain is able to

291
00:15:22.325 --> 00:15:27.005
bind a specific target and the affinity of that binding,

292
00:15:27.005 --> 00:15:28.445
so this is a functional feature.

293
00:15:29.145 --> 00:15:30.765
And it's important to understand

294
00:15:31.075 --> 00:15:35.205
that if fewer features are put into the claim,

295
00:15:35.345 --> 00:15:40.005
the broader the protection scope, the narrower, the

296

00:15:40.225 --> 00:15:42.205
scope or the more features

297
00:15:42.205 --> 00:15:46.845
that are put into the claim, the more narrow is the

298
00:15:47.065 --> 00:15:50.325
protection scope provided by that claim.

299
00:15:52.545 --> 00:15:54.765
So when you're filing a patent application,

300
00:15:54.765 --> 00:15:57.005
there are two very important things

301
00:15:57.005 --> 00:15:58.445
that I would like to stress.

302
00:15:59.265 --> 00:16:03.205
It is very important to file a patent application

303
00:16:03.205 --> 00:16:06.005
of good quality as that improves the chances

304
00:16:06.005 --> 00:16:07.965
of obtaining a granted patent, right?

305
00:16:08.585 --> 00:16:11.005
And also a granted patent, right, which is relevant

306
00:16:11.005 --> 00:16:13.045
for your business because it is commonly

307
00:16:13.105 --> 00:16:14.565
and mistakenly believed

308
00:16:14.915 --> 00:16:17.925
that a poor first application may be improved later

309
00:16:18.025 --> 00:16:22.885
and this is not true. It is not possible to change

310
00:16:23.225 --> 00:16:25.525
and improved a poor quality product

311
00:16:26.505 --> 00:16:30.045
and saving on this very early step will often lead

312
00:16:30.045 --> 00:16:31.365
to much higher costs later

313
00:16:31.545 --> 00:16:35.765
and also may lead to not obtaining the desired protection.

314
00:16:36.345 --> 00:16:38.125
So it is very important to put

315
00:16:38.765 --> 00:16:41.925
resources into this very early steps of the process

316
00:16:43.185 --> 00:16:45.685

and the filing of the first patent application.

317

00:16:45.945 --> 00:16:49.445

It also starts the clock for the next procedural steps

318

00:16:49.975 --> 00:16:53.445

which follow in a predetermined timeline.

319

00:16:55.305 --> 00:16:57.565

So if you file a first patent application

320

00:16:57.665 --> 00:17:01.365

and you want the, um, obtain patent in other countries

321

00:17:01.365 --> 00:17:04.525

for the same invention, you need to apply for the patent

322

00:17:04.785 --> 00:17:07.605

for the same invention in other countries within 12 months

323

00:17:08.155 --> 00:17:09.765
with what we call priority.

324
00:17:10.625 --> 00:17:12.645
So priority means that the filing date

325
00:17:12.645 --> 00:17:15.285
of the first application is used for the evaluation

326
00:17:15.285 --> 00:17:19.005
of patentability in light of the prior art for

327
00:17:19.035 --> 00:17:21.325
that invention, even in those other countries.

328
00:17:22.625 --> 00:17:26.845
And if you wish to

329
00:17:26.935 --> 00:17:29.165
start the clock over, if you don't want to continue,

330
00:17:29.185 --> 00:17:31.205
you must withdraw that first application,

331
00:17:31.215 --> 00:17:32.805
never let it become public

332
00:17:32.905 --> 00:17:35.125
and never use that priority, right?

333
00:17:35.825 --> 00:17:38.125
So you start a

334
00:17:40.075 --> 00:17:44.165
predetermined pattern

335
00:17:44.265 --> 00:17:46.965
of events when you file a patent application

336
00:17:47.065 --> 00:17:51.125
and it's important to understand that you need

337
00:17:51.125 --> 00:17:54.125
to follow this timeline.

338
00:17:58.785 --> 00:18:02.245
So let's discuss a little bit about the data in the patent

339
00:18:02.245 --> 00:18:05.205
application because data is very important in

340
00:18:05.205 --> 00:18:06.245
the biology field.

341
00:18:07.025 --> 00:18:10.325
So well, of course an invention needs to be new,

342
00:18:10.395 --> 00:18:13.445
like we said, and it has to have inventive step.

343
00:18:14.065 --> 00:18:18.285

But the law also requires that the inventor in order,

344
00:18:18.345 --> 00:18:21.645
to be rewarded the exclusivity of a patent, has

345
00:18:21.645 --> 00:18:24.965
to disclose the invention so that others can develop

346
00:18:25.545 --> 00:18:28.005
it further, they can build upon it.

347
00:18:28.185 --> 00:18:30.445
And this is sort of what is called the patent bargain.

348
00:18:32.665 --> 00:18:36.205
And so how do we, in biotechnology,

349
00:18:37.525 --> 00:18:39.085
disclose and describe our inventions?

350

00:18:39.085 --> 00:18:42.085
Well, this is what data, so data in the application required

351
00:18:42.085 --> 00:18:44.325
to support the claim dimension

352
00:18:44.865 --> 00:18:47.925
and it's supposed to be detailed enough in order

353
00:18:47.985 --> 00:18:49.325
to enable a skilled person

354
00:18:49.385 --> 00:18:51.925
to practice the invention without any undue burden.

355
00:18:53.425 --> 00:18:54.725
So if we have data

356
00:18:54.745 --> 00:18:57.325
and patent application, for example, showing

357

00:18:57.355 --> 00:19:01.325

that our technology works in a very few settings,

358

00:19:01.555 --> 00:19:05.485

then we may likely obtain a narrow protection scope.

359

00:19:05.635 --> 00:19:09.485

However, if you have several experiments showing that

360

00:19:09.755 --> 00:19:13.365

your technology works in different settings, in different,

361

00:19:13.705 --> 00:19:18.085

I dunno, different generations of car cells

362

00:19:18.745 --> 00:19:21.645

then we

363

00:19:22.715 --> 00:19:24.325

then you may be rewarded.

364

00:19:24.325 --> 00:19:25.325

Broad protection scope

365

00:19:25.905 --> 00:19:29.645

and data is also considered for the plausibility.

366

00:19:30.385 --> 00:19:34.485

So plausibility criteria will look the next slide on,

367

00:19:34.505 --> 00:19:39.165

but I just want to stress the balance between early filing

368

00:19:39.555 --> 00:19:42.965

with narrow data and broad file

369

00:19:43.105 --> 00:19:45.005

and late filing with broader data.

370

00:19:45.825 --> 00:19:50.805

It is a balance between being the first to file

371
00:19:50.945 --> 00:19:53.045
and collecting more data in order

372
00:19:53.045 --> 00:19:54.325
to get a broad protection scope.

373
00:19:54.985 --> 00:19:59.965
And just to comment from a patent perspective,

374
00:20:00.315 --> 00:20:04.245
it's much better to have few experiments on

375
00:20:05.225 --> 00:20:07.125
in many different settings than

376
00:20:08.085 --> 00:20:11.005
detailed data on one specific embodiment

377

00:20:11.005 --> 00:20:14.485
because even though you have very, a lot

378
00:20:14.485 --> 00:20:17.125
of detailed data on that specific embodiment,

379
00:20:17.265 --> 00:20:20.325
you cannot generalize it to a broader protection scope.

380
00:20:22.385 --> 00:20:27.045
So, as I said, plausibility, this is where the data come,

381
00:20:28.305 --> 00:20:31.205
is used for extrapolation,

382
00:20:32.065 --> 00:20:33.565
based on the data.

383
00:20:33.565 --> 00:20:36.005
Where the question asked is

384

00:20:36.235 --> 00:20:39.285

does the disclosure in the patent application make it

385

00:20:39.285 --> 00:20:40.645

plausible for the skilled person

386

00:20:40.715 --> 00:20:42.805

that the invention will work the way

387

00:20:42.805 --> 00:20:46.485

that he the is stipulated in the patent application?

388

00:20:47.585 --> 00:20:51.445

So a typical example of this is a therapeutic effect.

389

00:20:52.025 --> 00:20:54.205

Is it made plausible based on the data

390

00:20:54.205 --> 00:20:55.685

presented in the application?

391
00:20:56.275 --> 00:20:58.125
Well, if the data is clinical data,

392
00:20:58.235 --> 00:20:59.925
then obviously the answer is yes.

393
00:21:00.385 --> 00:21:02.285
But if you only have in vivo data

394
00:21:02.985 --> 00:21:04.325
in your patent application,

395
00:21:04.435 --> 00:21:06.605
well then we might discuss plausibility,

396
00:21:06.785 --> 00:21:10.325
but if you have chosen a well, uh, well characterized model,

397
00:21:11.105 --> 00:21:15.245

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then you may have a strong case for plausibility.

398
00:21:16.305 --> 00:21:18.965
Um, however, if you only have in vitro data,

399
00:21:19.475 --> 00:21:23.245
your case is definitely less strong.

400
00:21:24.425 --> 00:21:28.845
So the data is used

401
00:21:29.025 --> 00:21:31.725
for several things in the patent application.

402
00:21:33.665 --> 00:21:35.525
So a common filing strategy.

403
00:21:35.795 --> 00:21:39.045
Well, in order to get some as much patent time as possible,

404

00:21:39.545 --> 00:21:43.805
it is common to do first filing of a patent application

405
00:21:43.945 --> 00:21:44.965
in a country of choice,

406
00:21:45.145 --> 00:21:48.685
and then use this patent application to claim priority from.

407
00:21:49.825 --> 00:21:52.565
So in order to buy time and postpone costs,

408
00:21:53.025 --> 00:21:55.645
and in order to efficiently reach as many countries

409
00:21:55.645 --> 00:21:57.125
with your application as possible,

410
00:21:57.965 --> 00:22:01.245
a PCT application is usually done filed.

411

00:22:01.785 --> 00:22:04.365

And this application, it does not itself lead

412

00:22:04.365 --> 00:22:07.645

to a granted patent, however, it is a centralized search

413

00:22:07.645 --> 00:22:08.845

and examination process,

414

00:22:10.065 --> 00:22:13.525

and that international application can be then taken

415

00:22:13.755 --> 00:22:14.885

into different countries.

416

00:22:15.185 --> 00:22:20.125

So 30 to 31 months from the priority filing, you may need

417

00:22:20.125 --> 00:22:23.805

to make an important business decision to choose

418

00:22:23.875 --> 00:22:26.605

what countries you want to prosecute your patent in

419

00:22:27.025 --> 00:22:28.805

and it's only in those countries chosen

420

00:22:28.815 --> 00:22:30.925

where you can actually obtain a granted patent.

421

00:22:32.185 --> 00:22:37.045

In Europe, we have a system where you can file that

422

00:22:37.665 --> 00:22:40.605

or regionalize your application at

423

00:22:40.605 --> 00:22:41.885

the European patent Office

424

00:22:42.425 --> 00:22:46.165

and the European Patent Office will examine

425
00:22:46.345 --> 00:22:47.525
and grant your patent,

426
00:22:47.985 --> 00:22:51.645
and then you can validate that patent in

427
00:22:51.835 --> 00:22:53.685
different European countries.

428
00:22:54.945 --> 00:22:57.885
And since the 1st of June of this year,

429
00:22:57.945 --> 00:23:01.765
we also have a system where we can obtain a European pattern

430
00:23:01.795 --> 00:23:03.125
with unitary effect.

431

00:23:03.705 --> 00:23:06.285
And that means that in a number of

432
00:23:06.725 --> 00:23:09.685
collaborating EU countries, European union countries,

433
00:23:10.615 --> 00:23:13.565
which are 17 in this collaboration at this time point,

434
00:23:14.145 --> 00:23:18.925
you can obtain one right covering all those countries.

435
00:23:20.785 --> 00:23:24.325
So let's now go on and look at life science inventions

436
00:23:24.325 --> 00:23:27.285
because life science has some challenges

437
00:23:27.315 --> 00:23:29.405
that other technology areas do not.

438

00:23:30.745 --> 00:23:34.045

So what are the life science inventions?

439

00:23:34.275 --> 00:23:37.325

Well in the field of biotechnology?

440

00:23:37.335 --> 00:23:40.405

While all inventions have to meet the same criteria

441

00:23:41.385 --> 00:23:44.805

as any other invention in terms of novelty, inventive step

442

00:23:44.865 --> 00:23:46.245

and industrial application.

443

00:23:47.395 --> 00:23:51.645

However there are also other special exceptions

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00:23:51.665 --> 00:23:54.605

to patentability in life science,

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445

00:23:54.825 --> 00:23:58.525

and I will talk to the about those soon.

446

00:23:59.185 --> 00:24:03.245

What I want to comment on is that within the field

447

00:24:03.265 --> 00:24:08.045

of biotech or life science, it is more

448

00:24:08.615 --> 00:24:11.925

often that a patent is refused than in other

449

00:24:11.925 --> 00:24:12.965

fields of technologies.

450

00:24:13.155 --> 00:24:15.845

Only 30% of patents

451

00:24:15.905 --> 00:24:18.325

in Europe are granted in the field

452
00:24:18.325 --> 00:24:21.245
of biotechnology in contrast to

453
00:24:21.425 --> 00:24:24.885
the average 50% in other technology areas.

454
00:24:26.905 --> 00:24:29.685
So life science interventions: well, in addition

455
00:24:29.685 --> 00:24:31.965
to those regular patentability criteria,

456
00:24:31.965 --> 00:24:34.725
there's some special considerations in this field.

457
00:24:35.585 --> 00:24:39.845
And in the European legal system

458

00:24:39.855 --> 00:24:42.125
there are some exemptions, dependability

459
00:24:42.585 --> 00:24:45.365
and these are based on ethical and moral considerations.

460
00:24:46.105 --> 00:24:49.085
So patents are not to hinder healthcare professionals in the

461
00:24:49.085 --> 00:24:50.245
professional activities,

462
00:24:50.625 --> 00:24:53.165
and they're supposed to allow for good patient care.

463
00:24:54.025 --> 00:24:58.485
So in Europe the law says that methods of treatments,

464
00:24:58.485 --> 00:25:01.365
surgery or diagnosis on the patient's body

465

00:25:01.505 --> 00:25:02.685

are not patentable.

466

00:25:03.035 --> 00:25:05.725

However, products that are used in such processes,

467

00:25:05.755 --> 00:25:09.365

they may be patentable. In the US if solved this

468

00:25:09.545 --> 00:25:12.285

same issue with a different approach

469

00:25:13.135 --> 00:25:17.085

where in the US methods of treatments are patentable.

470

00:25:17.635 --> 00:25:21.085

However, health professionals are exempted from infringement

471

00:25:21.185 --> 00:25:24.205

in their professional activities.

472

00:25:25.795 --> 00:25:29.485

However, diagnostic methods they're becoming increasingly

473

00:25:30.115 --> 00:25:32.685

hard to protect in the US

474

00:25:33.185 --> 00:25:37.525

and they are also often seen as not

475

00:25:38.045 --> 00:25:40.925

actually adding more or being nothing more than natural

476

00:25:41.115 --> 00:25:43.645

processes occurring in the body.

477

00:25:45.905 --> 00:25:48.525

So this has of course, bearing on

478

00:25:49.235 --> 00:25:51.725

what can be protected in different jurisdictions

479
00:25:51.725 --> 00:25:53.565
and how we can protect that.

480
00:25:54.825 --> 00:25:59.085
So, also we have exemptions in Europe which say that

481
00:26:00.065 --> 00:26:01.365
thehuman body

482
00:26:01.545 --> 00:26:05.045
and its parts including gene sequences are not patentable.

483
00:26:05.045 --> 00:26:07.765
However, if they are isolated from their national

484
00:26:07.765 --> 00:26:09.725
environment, they may be patentable.

485

00:26:10.355 --> 00:26:14.605
This is in contrast to the case in the US where patents

486
00:26:14.605 --> 00:26:16.725
for a product in any field of technology

487
00:26:17.545 --> 00:26:20.565
are not allowed if the same product can be found in nature.

488
00:26:21.105 --> 00:26:24.445
So this is even if a product has been isolated from its

489
00:26:24.445 --> 00:26:26.565
natural environment, for example, a gene sequence.

490
00:26:27.785 --> 00:26:32.565
So it is important when you're drafting a patent

491
00:26:32.565 --> 00:26:36.165
application to keep all these differences in mind nd

492

00:26:36.165 --> 00:26:39.165

because you need to adapt your drafting style

493

00:26:39.225 --> 00:26:43.245

and what, how your patent claims are written

494

00:26:44.305 --> 00:26:46.965

for the different requirements posed

495

00:26:46.965 --> 00:26:48.405

by the law in different jurisdictions

496

00:26:48.405 --> 00:26:51.885

and you have to do this from the beginning. This slide

497

00:26:52.525 --> 00:26:56.845

summarizes the law that we just talk

498

00:26:56.845 --> 00:26:59.765

about the differences between the European

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00:27:00.345 --> 00:27:03.885

and the US law in terms what is patentable in the

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00:27:04.515 --> 00:27:07.285

life science and biotechnology field.

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00:27:10.065 --> 00:27:12.685

So the ATMP field, it's quickly evolving,

502

00:27:12.985 --> 00:27:16.045

and along with it patent practice is currently developing

503

00:27:16.145 --> 00:27:18.925

and adapting and unlike small molecules

504

00:27:18.925 --> 00:27:21.605

which can be characterized by the chemical structure

505

00:27:21.705 --> 00:27:23.965

or biologics that can be described by a sequence

506
00:27:23.985 --> 00:27:25.205
of glycosylation pattern

507
00:27:25.265 --> 00:27:29.925
and so on, a cell which

508
00:27:30.025 --> 00:27:32.805
is used in cell therapy, it's a complex living entity.

509
00:27:33.425 --> 00:27:36.685
And in that sense, this field poses new challenges on how

510
00:27:36.685 --> 00:27:39.765
to protect inventions in a way that goes hand in hand

511
00:27:39.835 --> 00:27:41.005
with new business models.

512

00:27:41.865 --> 00:27:45.405
And despite the exceptions, dependability, multiple aspects

513
00:27:45.405 --> 00:27:47.405
of cell and gene therapies are eligible

514
00:27:47.405 --> 00:27:48.485
for patent protection.

515
00:27:48.945 --> 00:27:51.445
So in general, a genetic constructs, vectors

516
00:27:51.445 --> 00:27:53.885
and genetically modified cells are patentable.

517
00:27:54.465 --> 00:27:57.365
For example, if a cell population is structurally

518
00:27:57.425 --> 00:28:00.205
or functionally distinct from previously described

519

00:28:00.205 --> 00:28:03.405

populations of cell, it may principle be protected.

520

00:28:04.195 --> 00:28:08.565

However, if for example, the population's patient specific,

521

00:28:08.785 --> 00:28:13.085

it may be difficult to obtain a product protection

522

00:28:13.215 --> 00:28:15.685

which captures the product sufficiently.

523

00:28:15.825 --> 00:28:18.925

So for many therapies, claims to modify populations

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00:28:18.945 --> 00:28:21.565

of cells expressing specific constructs may be suitable

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00:28:22.305 --> 00:28:23.925

as well as claims to the constructs

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00:28:23.925 --> 00:28:27.285

as such, the genes, the peptides, the vectors themselves,

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00:28:27.285 --> 00:28:28.645

which are used for manipulation.

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00:28:30.065 --> 00:28:33.245

And even where cell population not structurally

529

00:28:33.245 --> 00:28:36.005

or functionally distinct from previously known populations,

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00:28:36.435 --> 00:28:39.165

then protecting the method used to obtain

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00:28:39.195 --> 00:28:42.005

that cell population may be very valuable,

532

00:28:42.585 --> 00:28:44.845

for example, such as methods of culturing

533
00:28:44.865 --> 00:28:47.805
or differentiation, manipulation or preservation of cells.

534
00:28:48.465 --> 00:28:50.325
So patterns relating to treatment

535
00:28:50.385 --> 00:28:53.485
and treatment regimens may also play an important role in

536
00:28:53.485 --> 00:28:55.885
patent portfolios in the ATMP field

537
00:28:57.025 --> 00:29:00.085
and in the case where cells are patient specific

538
00:29:00.225 --> 00:29:02.485
and one cannot define them in common features,

539

00:29:02.505 --> 00:29:05.245
method protections likely to be very

540
00:29:05.435 --> 00:29:06.685
much important indeed.

541
00:29:07.275 --> 00:29:10.405
However, if the product is an off shelf product

542
00:29:10.585 --> 00:29:13.325
and off the shelf, for example, cell therapy product,

543
00:29:13.435 --> 00:29:16.445
then product protection is particularly desirable

544
00:29:17.545 --> 00:29:20.245
and in vitro differentiated cells

545
00:29:20.265 --> 00:29:23.445
and stem cells populations

546

00:29:23.445 --> 00:29:26.765

of those may be patentable if it can be distinguished from

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00:29:26.765 --> 00:29:29.325

other previously described cells

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00:29:29.385 --> 00:29:31.325

and in the US of course, also from the cells

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00:29:31.325 --> 00:29:32.925

that are naturally occurring in the body.

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00:29:33.345 --> 00:29:36.565

And this may be challenging, then again,

551

00:29:36.565 --> 00:29:39.205

the method protection may be very important.

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00:29:40.505 --> 00:29:43.885

So let's look a little more in detail at cell

553
00:29:43.945 --> 00:29:46.725
and gene therapy and IP in that field.

554
00:29:48.985 --> 00:29:51.525
So recent scientific breakthroughs have led

555
00:29:51.525 --> 00:29:53.165
to the development of this new class

556
00:29:53.165 --> 00:29:54.485
of therapeutic approaches,

557
00:29:54.895 --> 00:29:58.005
which challenge common strategies on intellectual property

558
00:29:58.105 --> 00:30:02.525
and market exclusivity and cell and gene therapies,

559
00:30:02.525 --> 00:30:03.805

they represent the cutting edge

560
00:30:03.805 --> 00:30:05.285
of modern medicine in many ways,

561
00:30:06.065 --> 00:30:08.925
but are also associated with high development costs

562
00:30:08.985 --> 00:30:10.205
and high production costs.

563
00:30:11.025 --> 00:30:15.005
So cell therapy, it harnesses the

564
00:30:15.635 --> 00:30:18.965
potential of living transplanted cells into patients

565
00:30:19.025 --> 00:30:20.605
to achieve therapeutic results.

566

00:30:21.465 --> 00:30:25.885
And the areas of treatment, of course, include a

567
00:30:26.505 --> 00:30:29.245
lot of different fields including oncology, immunology,

568
00:30:29.245 --> 00:30:32.045
neurology, rheumatology and so on.

569
00:30:33.225 --> 00:30:35.965
Um, so if you just consider the gene

570
00:30:36.595 --> 00:30:39.645
cell therapy relates to transfer of intact

571
00:30:39.645 --> 00:30:42.005
and live cells into patient to lessen

572
00:30:42.005 --> 00:30:44.165
or cure a disease.

573

00:30:44.305 --> 00:30:46.885

And then the cells may originate from the patient

574

00:30:47.465 --> 00:30:49.685

or they may be donor, come from a donor.

575

00:30:50.225 --> 00:30:52.165

And gene therapy is the modification

576

00:30:52.225 --> 00:30:55.005

or the manipulation deletion of genes to treat,

577

00:30:55.085 --> 00:30:56.365

prevent or cure disease.

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00:30:56.785 --> 00:30:59.525

And there are two types of gene therapy we can consider: in

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00:30:59.555 --> 00:31:00.845

vivo or ex vivo.

Una subvención de educación médica independiente respaldada en colaboración por la Sociedad Americana de Terapia Génica y Celular y Pfizer.

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00:31:02.265 --> 00:31:03.325

One

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00:31:03.325 --> 00:31:07.085

of the most known we cell therapy approaches is the

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00:31:07.085 --> 00:31:10.045

immunotherapy, which uses chimeric antigen receptor T cells

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00:31:10.585 --> 00:31:13.205

to potentate the ability to fight cancer.

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00:31:13.825 --> 00:31:16.365

So CAR T fusion proteins that use

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00:31:16.925 --> 00:31:20.005

a single chain variable fragments from antibody field

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00:31:20.265 --> 00:31:23.245

Una subvención de educación médica independiente respaldada en colaboración por la Sociedad Americana de Terapia Génica y Celular y Pfizer.

to allow specific targeting by immune cells to cells

587
00:31:23.935 --> 00:31:25.525
expressing target antigen,

588
00:31:25.865 --> 00:31:27.445
and the immune cells elicit an

589
00:31:27.445 --> 00:31:29.085
immune response to kill those cells.

590
00:31:30.665 --> 00:31:33.325
The CAR T constructs often

591
00:31:33.595 --> 00:31:36.525
also contain costimulatory domains

592
00:31:36.525 --> 00:31:38.205
to potent shape the immune response,

593

00:31:38.305 --> 00:31:40.165
and we'll dwell somewhat on this example

594
00:31:40.825 --> 00:31:43.485
and other therapeutic approaches include treatment

595
00:31:43.485 --> 00:31:46.405
of patients with living cells with stem cells

596
00:31:46.405 --> 00:31:50.045
and vitro differentiated cells, donor cells from

597
00:31:50.605 --> 00:31:54.605
patients themselves or from established cell lines.

598
00:31:58.905 --> 00:32:03.885
So it we've just considered gene therapy, like we said,

599
00:32:03.885 --> 00:32:07.765
it was the modification, manipulation, deletion of genes

600
00:32:07.765 --> 00:32:09.605
to treat, prevent or cure disease.

601
00:32:10.745 --> 00:32:14.405
And we have the example of in vivo therapy

602
00:32:15.335 --> 00:32:20.165
where

603
00:32:20.165 --> 00:32:22.845
that the therapy is administered directly

604
00:32:22.985 --> 00:32:25.445
by packaging a gene of interest into viral

605
00:32:25.465 --> 00:32:27.685
or non-viral vector and then injecting the

606
00:32:27.885 --> 00:32:29.005
treatment into the patient.

607

00:32:29.705 --> 00:32:31.685

In contrast, we have the ex vivo therapy

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00:32:31.855 --> 00:32:35.645

where cells are isolated from the patient, they're modified,

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00:32:35.865 --> 00:32:39.645

in the lab, and then that cell population is expanded

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00:32:40.425 --> 00:32:44.405

and the cells are returned to the patient. And gene therapy.

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00:32:44.705 --> 00:32:49.525

Um, it began nearly 80 years ago when

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00:32:49.885 --> 00:32:53.405

a gentleman called Clyde E. Keeler conceptualized the practice

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00:32:53.405 --> 00:32:55.405

of correcting genes and plants and animals

614
00:32:56.465 --> 00:32:58.805
and research into this field

615
00:32:59.595 --> 00:33:02.405
increased tremendously in the 60s and 70s

616
00:33:03.305 --> 00:33:07.245
and there were a lot of clinical trials at the beginning

617
00:33:07.505 --> 00:33:09.965
of the millennium.

618
00:33:10.355 --> 00:33:12.365
However, then progress came to hold

619
00:33:12.365 --> 00:33:16.845
because a young teenager who suffered from a

620

00:33:17.605 --> 00:33:22.285
metabolic disease

621
00:33:22.635 --> 00:33:27.045
upon receiving a gene therapy treatment died

622
00:33:27.915 --> 00:33:32.165
with quite quickly his health did deteriorate

623
00:33:32.165 --> 00:33:34.165
after the treatment and he passed away.

624
00:33:34.905 --> 00:33:38.285
And this set back the field quite a lot.

625
00:33:38.675 --> 00:33:43.645
However the field has rebounded

626
00:33:44.265 --> 00:33:49.045
and today we have I believe about well close

627
00:33:49.045 --> 00:33:52.845
to 30 cell and gene therapy products approved

628
00:33:52.905 --> 00:33:54.565
by the FDA in the US

629
00:33:54.905 --> 00:33:59.245
and there are over 1,200 clinical trials

630
00:33:59.765 --> 00:34:02.045
registered in this technology field.

631
00:34:04.185 --> 00:34:08.285
We talked a little about about patenting

632
00:34:08.425 --> 00:34:09.805
of genes in Europe

633
00:34:10.025 --> 00:34:13.205
and in the US snd just as a reminde

634
00:34:13.495 --> 00:34:16.805
there are two different approaches to

635
00:34:17.395 --> 00:34:18.845
patenting of genes.

636
00:34:19.025 --> 00:34:21.845
When they're isolated

637
00:34:22.755 --> 00:34:26.565
from their natural environment in Euro Europe, they are

638
00:34:26.775 --> 00:34:31.525
patentable subject matter, even if they exactly correspond

639
00:34:31.745 --> 00:34:33.085
to what is in the body.

640
00:34:33.905 --> 00:34:36.805

In contrast in the US

641
00:34:38.185 --> 00:34:40.285
an isolated product, if it's identical

642
00:34:40.505 --> 00:34:44.285
to naturally occurring product, it is not within

643
00:34:44.545 --> 00:34:46.725
the patentable subject matter.

644
00:34:47.105 --> 00:34:50.805
If it is not a naturally occurring product,

645
00:34:50.905 --> 00:34:51.965
it may be patented.

646
00:34:54.185 --> 00:34:58.925
So if we dwell a little bit on the vectors used for delivery

647

00:34:59.065 --> 00:35:03.405
of gene therapy, we can look at the patent landscape

648
00:35:03.405 --> 00:35:04.845
and how it has been evolving.

649
00:35:06.025 --> 00:35:10.925
So we can clearly see that around 2014 -

650
00:35:11.065 --> 00:35:14.325
2015, there was a surge of

651
00:35:14.865 --> 00:35:19.525
fi patent filings relating to adeno associated viruses

652
00:35:19.705 --> 00:35:22.725
and the use of those for gene delivery.

653
00:35:23.825 --> 00:35:28.205
Simultaneously retroviral viruses,

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00:35:28.215 --> 00:35:31.925

viral vectors were also the number

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00:35:31.925 --> 00:35:34.845

of patent filings relating to those increased,

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00:35:35.065 --> 00:35:39.925

but it stagnated compared to the

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00:35:40.485 --> 00:35:42.285

adeno associated viruses.

658

00:35:43.825 --> 00:35:47.405

So the principle of using these viruses

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00:35:47.465 --> 00:35:48.845

or the different

660

00:35:50.085 --> 00:35:53.005

delivery system have already been the disclosed

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00:35:53.005 --> 00:35:57.085

and described both in patent and non patent literature.

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00:35:57.185 --> 00:35:58.805

So what can be protected today?

663

00:35:58.875 --> 00:36:01.085

Well, we can look at general improvements

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00:36:01.105 --> 00:36:02.245

of delivery systems

665

00:36:02.585 --> 00:36:05.845

and maybe those could be generalized of a

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00:36:06.435 --> 00:36:08.125

different areas.

667

00:36:08.425 --> 00:36:11.005

For example, it could relate to reduction of toxicity

668
00:36:11.065 --> 00:36:13.085
or reduction of immunogenicity.

669
00:36:14.265 --> 00:36:18.565
Specific vectors if you develop a new vector

670
00:36:18.905 --> 00:36:23.405
and you can most likely obtain protection for

671
00:36:23.595 --> 00:36:25.445
that vector specifically

672
00:36:25.505 --> 00:36:27.405
but that is a narrow protection scope.

673
00:36:28.105 --> 00:36:30.605
And then of course, specific constructs

674

00:36:30.665 --> 00:36:33.845
within those vectors defined by the genes

675
00:36:34.185 --> 00:36:37.285
for targeting a specific disease are also

676
00:36:37.285 --> 00:36:38.565
subject to patentability.

677
00:36:42.625 --> 00:36:44.245
And this slide illustrates

678
00:36:44.305 --> 00:36:47.725
how quickly this field has evolved from

679
00:36:48.635 --> 00:36:51.325
practically not existing

680
00:36:51.665 --> 00:36:54.925
and having first filings in the late 1980s

681
00:36:55.665 --> 00:36:59.405
to a large area with a large number of patent families.

682
00:37:00.225 --> 00:37:04.285
Well dating back

683
00:37:04.345 --> 00:37:07.445
to this graph is from 2018

684
00:37:08.425 --> 00:37:11.925
we also see what jurisdictions are dominating in this field

685
00:37:11.985 --> 00:37:14.365
and it's largely the US

686
00:37:14.585 --> 00:37:18.005
and also China with

687
00:37:18.835 --> 00:37:21.525
some other smaller jurisdictions

688
00:37:23.225 --> 00:37:25.045
also prominent.

689
00:37:25.825 --> 00:37:29.405
It's easy to find information about

690
00:37:29.475 --> 00:37:32.005
what entities are filing

691
00:37:32.785 --> 00:37:36.285
and being active in this field of technology as well

692
00:37:36.285 --> 00:37:40.405
and is illustrated in this graph where we see companies

693
00:37:40.465 --> 00:37:42.645
and universities that are well known

694
00:37:42.745 --> 00:37:45.125

and established in this technology field.

695

00:37:47.425 --> 00:37:51.885

So then we looked at some challenges

696

00:37:52.345 --> 00:37:56.725

or we can discuss some challenges with patenting

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00:37:57.595 --> 00:38:00.205

cell therapy or ex vivo gene therapy.

698

00:38:01.265 --> 00:38:03.085

So just as a principle

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00:38:03.185 --> 00:38:06.565

and a reminder, we'll have a brief look at a generic case

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00:38:06.565 --> 00:38:09.085

illustrating the principles

701

00:38:09.305 --> 00:38:12.965
and then focus on what challenges

702
00:38:12.965 --> 00:38:14.885
that poses from an IP perspective.

703
00:38:15.785 --> 00:38:18.765
So basically, the cells are derived from a patient

704
00:38:19.065 --> 00:38:20.645
or a donor or a cell line,

705
00:38:21.585 --> 00:38:24.405
and then these cells

706
00:38:25.265 --> 00:38:27.405
are then optionally manipulated.

707
00:38:28.985 --> 00:38:33.285
this could be genetic manipulation, could be exposure

708

00:38:33.305 --> 00:38:36.965

to extrinsic factors, expansions on specific conditions

709

00:38:37.065 --> 00:38:39.285

or selection for desirable properties

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00:38:40.465 --> 00:38:44.125

and such a population of cells is then proliferated,

711

00:38:44.505 --> 00:38:48.845

and this population is then exposed to some type

712

00:38:48.845 --> 00:38:53.285

of preparation where it is

713

00:38:54.115 --> 00:38:57.005

made into

714

00:38:57.315 --> 00:38:59.925

a product which could be administered to a patient

715
00:39:00.385 --> 00:39:02.525
and that patient could be either the same patient

716
00:39:02.795 --> 00:39:05.165
that derive that the cells were derived from

717
00:39:05.225 --> 00:39:06.445
or a different patient.

718
00:39:07.065 --> 00:39:09.885
So this is kind of a big picture overview of this case

719
00:39:10.025 --> 00:39:14.165
and if we just consider the case of CAR T cell therapy,

720
00:39:15.865 --> 00:39:19.165
each cell therapy product is based in specific,

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00:39:19.305 --> 00:39:21.365

so there is no off the shelf product,

722
00:39:21.935 --> 00:39:24.205
which poses the question of how

723
00:39:24.305 --> 00:39:26.725
to obtain the most useful patent protection

724
00:39:26.825 --> 00:39:28.165
and how can you protect the product.

725
00:39:29.225 --> 00:39:32.525
So at first stage of CAR T treatment is an extraction

726
00:39:32.525 --> 00:39:34.365
of the T-cells from the patient's body.

727
00:39:34.825 --> 00:39:37.565
And the cells are then set next center to a facility

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00:39:37.705 --> 00:39:40.565
for processing and manipulation in the laboratory involving

729
00:39:40.565 --> 00:39:42.365
genetic modification of the cells.

730
00:39:43.305 --> 00:39:47.405
And then by expression,

731
00:39:47.825 --> 00:39:51.885
to express synthetic cars which bind to particular target,

732
00:39:52.385 --> 00:39:54.445
expressed in the cancer tumor cells.

733
00:39:55.385 --> 00:39:59.125
So the modified t-cells are then the product which is then

734
00:39:59.605 --> 00:40:02.405
reintroduced into the same

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00:40:02.405 --> 00:40:05.045

patient's bloodstream at the care facility unit.

736

00:40:06.745 --> 00:40:09.125

And then inside the patient's body,

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00:40:09.385 --> 00:40:12.085

the cells are then attracted to the tumor cells

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00:40:12.085 --> 00:40:14.085

with their near new engineered cars,

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00:40:14.085 --> 00:40:16.245

which have affinity for the target protein.

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00:40:17.185 --> 00:40:20.325

And once the modified T cells bind to the tumor cells

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00:40:20.325 --> 00:40:23.685

they release the cytotoxic granules, attack the tumor cell

742
00:40:23.985 --> 00:40:25.125
and signal to all the cells

743
00:40:25.125 --> 00:40:27.205
of the immune system via cytokines

744
00:40:27.865 --> 00:40:29.365
to attack the tumor cells.

745
00:40:30.945 --> 00:40:34.085
So this process

746
00:40:35.215 --> 00:40:39.965
takes about 20 to 25 days from isolations of cells,

747
00:40:40.025 --> 00:40:42.205
the treatment of the patient and it's highly complex

748
00:40:42.625 --> 00:40:44.005

and highly costly

749
00:40:44.065 --> 00:40:47.285
and in view of this solid IP is very, very important.

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00:40:48.225 --> 00:40:50.925
So if the cell product as such can be protected, it needs

751
00:40:50.925 --> 00:40:52.965
to be defined in a way

752
00:40:52.995 --> 00:40:55.165
that covers heterogeneous populations,

753
00:40:55.635 --> 00:40:57.045
whereas it may be useful

754
00:40:57.045 --> 00:40:59.045
to attempt functional definition of a cell product

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00:40:59.105 --> 00:41:02.725
as such, it is becoming increasingly hard to obtain grants

756
00:41:02.785 --> 00:41:04.765
for claims with functional features alone.

757
00:41:05.185 --> 00:41:07.845
And then you need the structure features to complement that.

758
00:41:08.585 --> 00:41:11.845
And the structure features they may be given through a

759
00:41:12.915 --> 00:41:15.285
certain gene or

760
00:41:15.385 --> 00:41:18.205
constructs as gene or polypeptide.

761
00:41:18.905 --> 00:41:21.765
but also other products needed for the performance

762
00:41:21.965 --> 00:41:26.645
of cell therapy may include the

763
00:41:27.175 --> 00:41:29.685
viral vectors used for cell engineering.

764
00:41:30.225 --> 00:41:33.085
So that may offer a very valuable

765
00:41:33.165 --> 00:41:34.485
product protection scope.

766
00:41:36.025 --> 00:41:40.125
And then the whole process of manipulating

767
00:41:40.265 --> 00:41:43.405
and expanding the cells are also likely

768
00:41:43.505 --> 00:41:47.285
to have steps which are not unique for the particular cell,

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00:41:47.785 --> 00:41:49.845

cell therapy

770

00:41:50.025 --> 00:41:54.565

or cell culture from a specific, subject,

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00:41:54.745 --> 00:41:59.445

but could be used for different subjects.

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00:41:59.465 --> 00:42:03.605

And hence that is also a important protection scope.

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00:42:03.705 --> 00:42:05.405

So establishing production labs

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00:42:05.405 --> 00:42:08.325

and facilities, either your own that

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00:42:09.575 --> 00:42:11.005

which may be expensive

776
00:42:11.225 --> 00:42:13.325
or in collaboration with establish approved

777
00:42:13.345 --> 00:42:16.685
and validating facilities may increase, may indeed,

778
00:42:16.945 --> 00:42:19.325
create obstacles for competitors.

779
00:42:19.905 --> 00:42:23.765
And then of course, treatment regimens and dosage regimens.

780
00:42:23.765 --> 00:42:26.605
How often do you treat, how many cells do you

781
00:42:27.625 --> 00:42:29.405
do you administer and so on.

782

00:42:29.635 --> 00:42:33.245
That could also be subject for IP protection.

783
00:42:35.905 --> 00:42:40.605
So as I said, this is a quickly growing field with a lot

784
00:42:40.745 --> 00:42:42.205
of patent filings.

785
00:42:42.205 --> 00:42:46.045
Most applicants come from the US and China

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00:42:46.505 --> 00:42:49.965
and Europe is falling behind quite significantly.

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00:42:51.105 --> 00:42:55.405
And there is quite

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00:42:56.015 --> 00:42:58.805
large number of filings from research institutions,

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00:42:59.165 --> 00:43:02.845

research centers, and maybe 50% of the filings

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00:43:04.745 --> 00:43:06.845

come from companies.

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00:43:10.865 --> 00:43:15.765

So from a historical view, well early on during this

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00:43:15.765 --> 00:43:18.725

development of this technology, there was a small number

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00:43:18.725 --> 00:43:21.645

of applications and the patent protection scope

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00:43:21.835 --> 00:43:23.405

awarded was broad.

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00:43:24.265 --> 00:43:28.965

Here's a claim towards a composition comprising cells

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00:43:28.995 --> 00:43:32.205

that express car molecules that bind CD 19

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00:43:32.985 --> 00:43:37.165

and this definition is very broad

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00:43:37.385 --> 00:43:41.725

and it comes from a patent applications published

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00:43:41.725 --> 00:43:43.005

2015

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00:43:43.385 --> 00:43:48.085

and was where the applicant was Novartis.

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00:43:49.225 --> 00:43:52.965

So while at that time was still possible

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00:43:52.985 --> 00:43:56.565

to obtain a broad protection scope, kind of a generic

803
00:43:56.565 --> 00:43:58.885
protection scope today there is a large number

804
00:43:58.885 --> 00:43:59.965
of patent applications

805
00:44:00.465 --> 00:44:03.645
and all those patent applications cover narrow scope,

806
00:44:03.645 --> 00:44:05.605
they relate to improvement of technologies

807
00:44:06.545 --> 00:44:08.565
and improvement, can relate to

808
00:44:09.845 --> 00:44:12.725
improved biological activities, new targets,

809

00:44:13.845 --> 00:44:17.725
improved production, reduction of toxicity, and so on.

810
00:44:18.185 --> 00:44:22.765
And Just as an illustration of

811
00:44:22.765 --> 00:44:27.005
how quickly this field has evolved, this is

812
00:44:27.685 --> 00:44:28.925
PCT publications

813
00:44:28.985 --> 00:44:32.365
and international patents that have been published o over

814
00:44:32.665 --> 00:44:35.205
the years of the last decade.

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00:44:36.185 --> 00:44:39.125
2020, there was 2010

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00:44:39.135 --> 00:44:42.845

T

there was one patent application that was published

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00:44:42.875 --> 00:44:47.245

that year by what the applicant was the City of Hope.

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00:44:47.865 --> 00:44:49.445

And in 2019,

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00:44:49.825 --> 00:44:54.805

we had over 600 patent applications, new patent applications

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00:44:54.805 --> 00:44:58.405

that were filed, published in this technology area.

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00:44:58.505 --> 00:45:03.005

So there has been a very quick and fast development

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00:45:03.005 --> 00:45:04.485

and increase of patent filing.

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00:45:07.225 --> 00:45:10.965
And also we see actors

824
00:45:11.035 --> 00:45:13.445
that are very active in this field.

825
00:45:13.445 --> 00:45:16.165
There is quite a large number of different institutions

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00:45:16.165 --> 00:45:19.845
with Novartis and Juno therapeutics being

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00:45:20.395 --> 00:45:23.245
most prominent, but also University of California

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00:45:24.305 --> 00:45:28.605
and a number of actors which also have quite large patent

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00:45:29.085 --> 00:45:33.205
families over 30 patent

830
00:45:33.325 --> 00:45:35.325
applications pending in this field.

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00:45:35.465 --> 00:45:37.765
So there's a lot of activity here.

832
00:45:39.425 --> 00:45:43.365
So what can you patent within the CAR T field

833
00:45:43.505 --> 00:45:48.285
now? Recent patent applications, they relate mostly

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00:45:48.545 --> 00:45:51.565
as I said, to follow up inventions, improvements

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00:45:51.665 --> 00:45:53.045
of existing technologies,

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00:45:53.945 --> 00:45:56.405

and we can see a couple of groups

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00:45:56.505 --> 00:45:58.005

of these type of inventions.

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00:45:58.075 --> 00:46:00.365

Some are related to solving a problem

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00:46:00.365 --> 00:46:03.885

of the present technology, for example, toxicity of cells.

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00:46:04.825 --> 00:46:08.805

So CAR T therapy, they the

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00:46:09.415 --> 00:46:13.445

known problem to, uh, lead to neurotoxicity

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00:46:13.545 --> 00:46:15.045

and cytokine toxicity.

843
00:46:16.105 --> 00:46:20.085
So this could be addressed by turning off

844
00:46:20.085 --> 00:46:21.085
or turning on cells

845
00:46:21.145 --> 00:46:24.805
or inducible cells could improve the specificity,

846
00:46:25.275 --> 00:46:27.725
less off target, more on target binding,

847
00:46:28.505 --> 00:46:31.605
and maybe reduce cytokine production levels,

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00:46:32.585 --> 00:46:35.925
and challenges within this field is that,

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00:46:38.145 --> 00:46:42.085

Una subvención de educación médica independiente respaldada en colaboración por la Sociedad Americana de Terapia Génica y Celular y Pfizer.

the requires support in the data to show the

850
00:46:42.235 --> 00:46:44.765
this effect and establish inventive step

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00:46:44.835 --> 00:46:46.845
that it's actually an invention

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00:46:47.105 --> 00:46:48.885
to make these type of improvements.

853
00:46:49.505 --> 00:46:54.365
And in order to have a good application in this field,

854
00:46:54.395 --> 00:46:58.165
well, you're trying to make an improvement of technology.

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00:46:58.265 --> 00:47:01.325
So data that relating to comparative examples,

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00:47:01.325 --> 00:47:03.165
benchmarking will be very important.

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00:47:04.105 --> 00:47:06.725
And also consider whether they are

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00:47:06.875 --> 00:47:09.925
appropriate models used in those experiments

859
00:47:10.665 --> 00:47:12.645
and to define what is a good result,

860
00:47:12.995 --> 00:47:14.605
what is an improvement,

861
00:47:14.605 --> 00:47:16.245
what is a significant improvement

862
00:47:16.705 --> 00:47:19.685
and if this is technology is broadly applicable,

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00:47:19.685 --> 00:47:24.165

well then data is needed from different examples that show

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00:47:24.505 --> 00:47:26.645

broad usefulness.

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00:47:27.435 --> 00:47:29.450

Then on the other hand, we have inventions

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00:47:29.450 --> 00:47:30.805

relating to new targets.

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00:47:30.905 --> 00:47:33.365

So new target per se

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00:47:33.545 --> 00:47:36.245

or the new epitope on unknown target.

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00:47:37.185 --> 00:47:39.165

And a challenge here is of course,

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00:47:39.165 --> 00:47:42.285

that new targets may defining a new target may not be

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00:47:42.525 --> 00:47:45.525

sufficient to confer patentability in terms

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00:47:45.525 --> 00:47:46.645

of inventive step.

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00:47:47.665 --> 00:47:50.805

So most targets, they will already have been known

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00:47:50.865 --> 00:47:53.085

as markers associated with the disease,

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00:47:54.505 --> 00:47:57.245

and the new epitope can be considered just an alternative

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00:47:57.265 --> 00:47:58.645

to an existing epitope.

877
00:47:58.785 --> 00:48:01.445
So it may be much quite easy to obtain novelty,

878
00:48:01.445 --> 00:48:03.085
but inventive step is a challenge.

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00:48:03.545 --> 00:48:05.405
And again, the data

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00:48:05.665 --> 00:48:10.005
and one in these applications it is very important

881
00:48:10.465 --> 00:48:12.965
and it requires that

882
00:48:14.345 --> 00:48:16.525
it shows the effect, the advantage

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00:48:17.345 --> 00:48:20.525
and the advantage may not

884
00:48:20.825 --> 00:48:23.645
as such be obvious in the art as the advantage,

885
00:48:23.785 --> 00:48:25.925
it requires very careful planning of

886
00:48:25.925 --> 00:48:27.445
what comparative examples

887
00:48:27.465 --> 00:48:29.725
and to include in the patent application

888
00:48:29.745 --> 00:48:31.605
and what model system to use.

889
00:48:40.855 --> 00:48:43.085
Other examples here are

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00:48:43.205 --> 00:48:46.645

overcoming a biological problem, for example

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00:48:47.865 --> 00:48:49.445

the problem of solid tumors.

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00:48:49.445 --> 00:48:52.725

So how to overcome the tumor microenvironment

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00:48:52.745 --> 00:48:54.525

of a solid tumor

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00:48:54.745 --> 00:48:58.605

and how to overcome the problem of poor infiltration.

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00:48:59.545 --> 00:49:03.405

So again, the approach to modify cars, to induce features

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00:49:03.505 --> 00:49:07.885

to overcome tumor microenvironment is

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00:49:07.885 --> 00:49:09.805

what the technology is about.

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00:49:09.945 --> 00:49:12.925

And maybe that is to introduce functional modules into the

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00:49:12.925 --> 00:49:16.245

CARs or additional constructs to be expressed in the cells.

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00:49:16.625 --> 00:49:19.765

And here are also IP challenges.

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00:49:20.425 --> 00:49:24.085

If you have a general technology here,

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00:49:24.185 --> 00:49:26.205

it may be a platform technology that was

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00:49:26.205 --> 00:49:28.045

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with wide applicability.

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00:49:28.265 --> 00:49:29.445
And then it's very important

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00:49:29.635 --> 00:49:32.365
that the data in the patent application

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00:49:32.565 --> 00:49:34.805
supports the generalization and plausibility

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00:49:34.905 --> 00:49:37.525
so you need to consider choice of appropriate model

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00:49:37.585 --> 00:49:40.725
and also showing that the technology works in

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00:49:40.725 --> 00:49:41.965
different model backgrounds.

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00:49:43.145 --> 00:49:46.325
Then we have technology which relates

911
00:49:46.545 --> 00:49:48.845
to improvements in methods of production.

912
00:49:49.545 --> 00:49:52.525
So for example, one of the problems here is of course,

913
00:49:52.575 --> 00:49:56.485
along process with steps that could be optimized further,

914
00:49:56.635 --> 00:49:59.205
such as, for example, this transduction of cells.

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00:50:00.105 --> 00:50:02.925
And again, there's a potential broad applicability

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00:50:03.025 --> 00:50:05.165
of these type of technologies.

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00:50:05.545 --> 00:50:10.165

So if you want to protect the products

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00:50:10.165 --> 00:50:12.725

of these processes, then it's well important to consider

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00:50:12.945 --> 00:50:15.365

of these cells obtained

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00:50:15.385 --> 00:50:19.205

by an inventive method can be distinguished in any way

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00:50:19.275 --> 00:50:20.325

from known products.

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00:50:20.945 --> 00:50:24.845

Are there any features that are inherently in

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00:50:25.685 --> 00:50:28.085

incorporated into these cells

Una subvención de educación médica independiente respaldada en colaboración por la Sociedad Americana de Terapia Génica y Celular y Pfizer.

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00:50:28.745 --> 00:50:30.845

by the method used for their production.

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00:50:31.305 --> 00:50:33.605

And if no such features are there, then well,

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00:50:33.605 --> 00:50:36.405

novelty cannot be established for the product as such

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00:50:36.405 --> 00:50:40.365

then the method itself, uh, is the key to protect.

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00:50:41.145 --> 00:50:45.005

And if we just consider

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00:50:45.575 --> 00:50:48.485

three different variants of cell therapy,

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00:50:48.695 --> 00:50:50.125

three representative cases,

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00:50:51.035 --> 00:50:53.725
then we can look at genetically manipulated cells,

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00:50:54.025 --> 00:50:58.245
CAR T cells like we have talked about

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00:50:58.265 --> 00:50:59.485
for the past couple of minutes.

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00:50:59.585 --> 00:51:02.565
But we also have genetically un-manipulated cells,

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00:51:02.625 --> 00:51:05.365
for example, mesenchymal stem cells

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00:51:05.465 --> 00:51:07.245
or factor manipulated cells

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00:51:08.025 --> 00:51:10.605
and then we of course have cells which are

938
00:51:10.845 --> 00:51:13.005
derived from cell lines for example,

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00:51:13.025 --> 00:51:16.485
in vitro differentiated cells,

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00:51:16.485 --> 00:51:19.565
pancreatic beta cells, which would be

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00:51:20.525 --> 00:51:22.165
transplanted into patients.

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00:51:22.225 --> 00:51:24.805
And all these type of cells can be either autologous

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00:51:24.905 --> 00:51:26.205
or allogeneic.

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00:51:26.345 --> 00:51:30.765

And that itself poses challenges

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00:51:31.145 --> 00:51:32.605

on the IP side.

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00:51:33.345 --> 00:51:36.845

So if we just consider the autologous versus allogeneic

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00:51:36.845 --> 00:51:41.485

products and cell therapy, well autologous that relates

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00:51:41.625 --> 00:51:43.685

to tissues

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00:51:43.705 --> 00:51:46.245

or cells which are genetically similar with the recipients.

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00:51:46.245 --> 00:51:47.805

So the recipient here is a donor

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00:51:48.105 --> 00:51:50.285

and we're dealing with a patient specific product.

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00:51:51.305 --> 00:51:53.085

So the question is

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00:51:53.385 --> 00:51:56.045

can the product be defined in the general enough terms

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00:51:56.425 --> 00:52:00.125

to cover the autologous aspect and still be patentable?

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00:52:00.545 --> 00:52:04.325

So other functional features which should be sufficient

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00:52:04.465 --> 00:52:05.485

for this definition.

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00:52:05.945 --> 00:52:07.205

And again, like I said,

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00:52:07.445 --> 00:52:10.245
functional features alone are becoming increasingly hard,

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00:52:10.985 --> 00:52:12.805
so we might need structure features,

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00:52:12.825 --> 00:52:15.765
and the structure features need to be broad enough in our in

961
00:52:16.705 --> 00:52:20.045
to encompass all different autologous products.

962
00:52:20.785 --> 00:52:24.645
So this is a large challenge in the field.

963
00:52:26.185 --> 00:52:28.965
And then important to consider if there are any other

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00:52:29.595 --> 00:52:30.645
aspects of the product

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00:52:30.875 --> 00:52:32.645
that could be the focus of protection.

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00:52:33.025 --> 00:52:36.365
And here we come in with protection of the vectors used,

967
00:52:36.385 --> 00:52:39.445
the methods of productions are very, very important aspects.

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00:52:39.535 --> 00:52:43.405
Again, um, for an allogeneic product where

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00:52:43.545 --> 00:52:45.845
that's a product wherein the cells

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00:52:45.905 --> 00:52:49.445
or are genetically dissimilar with the recipients.

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00:52:49.465 --> 00:52:52.605

So usually it could be

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00:52:53.905 --> 00:52:55.925

or it could be two different products.

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00:52:55.925 --> 00:52:57.765

It can be an off-the-shelf product, of course.

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00:52:58.465 --> 00:53:00.845

And in that sense, it was really important

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00:53:00.945 --> 00:53:04.125

to obtain protection for the product as such.

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00:53:04.905 --> 00:53:09.685

Um, it can also be of course a product where the

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00:53:10.335 --> 00:53:12.485

donor is different than the recipient,

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00:53:13.145 --> 00:53:15.885

but how can you define this type of cell product

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00:53:16.305 --> 00:53:21.045

and is the donor matching step important or not?

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00:53:21.185 --> 00:53:24.565

And if it is important, then are there differences

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00:53:24.595 --> 00:53:28.845

between the products used for different recipients

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00:53:29.345 --> 00:53:32.925

and can we think of ways

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00:53:33.105 --> 00:53:34.325

of defining a product

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00:53:35.065 --> 00:53:39.445

wherein product protection

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00:53:39.445 --> 00:53:42.645
patent product protection covers the product despite

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00:53:42.665 --> 00:53:43.685
of the differences.

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00:53:45.505 --> 00:53:47.845
So this is indeed a

988
00:53:48.075 --> 00:53:50.725
very challenging area

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00:53:51.225 --> 00:53:55.685
and that field of technology, again

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00:53:56.415 --> 00:54:00.485
associated products are very important to protect as well

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00:54:00.705 --> 00:54:04.005
as methods of production.

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00:54:05.705 --> 00:54:06.805
So some of the aspects

993
00:54:06.805 --> 00:54:08.925
that we discussed here are also applicable

994
00:54:08.945 --> 00:54:12.005
to cells which have not been genetically manipulated,

995
00:54:12.005 --> 00:54:13.685
that is unmanipulated cells,

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00:54:13.945 --> 00:54:16.965
but cells that have in some way been processed into

997
00:54:16.965 --> 00:54:17.965
therapeutic composition.

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00:54:18.065 --> 00:54:20.005

And these could be stem cells such

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00:54:20.205 --> 00:54:22.885

as mesenchymal stem cells derived from donors.

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00:54:23.985 --> 00:54:27.245

And one very important challenge here is to how

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00:54:27.245 --> 00:54:29.965

to distinguish such populations from the prior art, how

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00:54:29.965 --> 00:54:31.245

to establish novelty.

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00:54:31.945 --> 00:54:35.365

And these are the challenges comes from two directions.

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00:54:35.385 --> 00:54:36.925

In one hand, you need

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00:54:36.925 --> 00:54:39.765
to distinguish them from the endogenous population,

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00:54:39.765 --> 00:54:40.925
particularly in the US

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00:54:40.975 --> 00:54:44.645
where naturally occurring products are not patentable,

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00:54:44.945 --> 00:54:47.685
but also from prior art, which often describes

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00:54:47.705 --> 00:54:50.365
as populations either treated by similar factors

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00:54:50.545 --> 00:54:52.525
or isolated from the relevant tissue.

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00:54:53.705 --> 00:54:58.565

So here again, product the products may themselves,

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00:54:58.625 --> 00:55:01.085
may not be patentable,

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00:55:01.385 --> 00:55:04.565
but the process of obtaining such product may be

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00:55:05.265 --> 00:55:07.445
and these could relate to use of stimulants

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00:55:07.545 --> 00:55:10.805
or mixing of populations in certain ways, screening

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00:55:10.805 --> 00:55:12.725
for certain properties

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00:55:12.725 --> 00:55:17.245
and selecting a subset of the population for with the

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00:55:17.835 --> 00:55:20.445
desirable properties or culture conditions.

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00:55:21.145 --> 00:55:23.805
So again, method protection is really

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00:55:23.805 --> 00:55:25.485
important in this area.

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00:55:25.825 --> 00:55:29.085
And as a last example we consider cells

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00:55:29.085 --> 00:55:31.645
that originate from a cell line such as ES cells

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00:55:31.645 --> 00:55:32.925
or from IPS cells,

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00:55:33.105 --> 00:55:35.605
and that are differentiated into cell product,

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00:55:35.735 --> 00:55:37.805

which we may be used for a therapeutic purpose.

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00:55:38.025 --> 00:55:40.805

For example, pancreatic beta cells, like I

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00:55:41.555 --> 00:55:42.765

mentioned previously.

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00:55:43.345 --> 00:55:45.645

And here is an inherent issue with the technology

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00:55:45.645 --> 00:55:46.805

because the goal is

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00:55:46.805 --> 00:55:48.725

to provide a cell population which mimics

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00:55:48.725 --> 00:55:49.765

the in vivo population.

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00:55:51.145 --> 00:55:53.485

So if we look at the population itself,

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00:55:53.665 --> 00:55:57.885

the way it is characterized pancreatic beta cells then

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00:55:57.885 --> 00:55:59.445

that is a product of nature

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00:55:59.825 --> 00:56:01.325

and should fall under the exemption

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00:56:01.345 --> 00:56:03.405

of from patentability in the US.

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00:56:03.715 --> 00:56:05.245

However, maybe it's possible

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00:56:05.265 --> 00:56:08.485

to just pinpoint some distinguishing features, which are

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00:56:09.065 --> 00:56:11.805
an accidental or purposeful artifact from the

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00:56:11.805 --> 00:56:14.205
differentiation process in vitro

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00:56:14.865 --> 00:56:17.805
and that may be able to overcome this aspect.

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00:56:18.585 --> 00:56:22.485
But generally, again, methods for differentiation

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00:56:22.755 --> 00:56:25.445
improvement of culture, conditions, substrates factors,

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00:56:25.545 --> 00:56:28.645
and timing during the differentiation process

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00:56:28.945 --> 00:56:32.245
may be key for obtaining method protection.

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00:56:32.865 --> 00:56:35.805
And here it is important with comparative examples

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00:56:35.905 --> 00:56:37.205
to show better properties

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00:56:37.205 --> 00:56:40.765
of the cells obtained using the inventive method compared

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00:56:40.785 --> 00:56:44.165
to cells obtainable by prior art methods

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00:56:44.945 --> 00:56:47.405
may the method that is the subject

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00:56:47.425 --> 00:56:50.125
of the new invention provides better efficiency,

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00:56:50.305 --> 00:56:55.125

better differentiation

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00:56:55.825 --> 00:56:57.325

and so on.

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00:56:58.065 --> 00:57:01.405

And also again, treatment regimens and dosage regimens

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00:57:02.105 --> 00:57:04.725

and maybe of relevance

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00:57:04.725 --> 00:57:07.445

but also, and this goes for all the different types

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00:57:07.505 --> 00:57:09.765

of therapies cause to consider if there are ways

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00:57:09.765 --> 00:57:12.005

of preparing a patient for receiving a therapy

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00:57:12.575 --> 00:57:15.245

which may be subject to protection.

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00:57:18.265 --> 00:57:21.085

So if your technology relates to cell population,

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00:57:21.085 --> 00:57:25.525

where there are some things that you can ask yourself.

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00:57:26.005 --> 00:57:28.605

Claiming a cell population product that poses a challenge

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00:57:28.665 --> 00:57:32.085

of characterizing that population, identifying features

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00:57:32.085 --> 00:57:33.965

that distinguish it from the prior art.

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00:57:34.785 --> 00:57:38.085

So how could you define a population?

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00:57:38.195 --> 00:57:40.965

Well are the function structural features that you can use,

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00:57:40.995 --> 00:57:42.845

such as markers

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00:57:42.905 --> 00:57:46.205

or proliferation rate, the way that your population responds

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00:57:46.205 --> 00:57:48.965

to stimulate the source of the population

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00:57:49.185 --> 00:57:51.285

or how the cells are engineered.

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00:57:51.505 --> 00:57:53.365

That could differ from case to case,

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00:57:53.625 --> 00:57:55.205
but the key here is to

1073
00:57:56.385 --> 00:57:58.765
ask yourself whether your population is a novel

1074
00:57:58.905 --> 00:58:00.685
or is it merely a characterization

1075
00:58:00.705 --> 00:58:02.485
of previously known population?

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00:58:03.025 --> 00:58:05.885
And if it is truly novel, then it may be patentable,

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00:58:05.945 --> 00:58:08.565
but if it's merely characterizations, likely not.

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00:58:09.425 --> 00:58:12.845
So it is very important to plan experiments

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00:58:13.155 --> 00:58:14.925

with this question in mind in order

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00:58:14.945 --> 00:58:18.285

to facilitate the patent granting process.

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00:58:21.665 --> 00:58:24.525

And then of course, protection of products,

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00:58:24.775 --> 00:58:28.645

again, the challenges that cells are complex living entities

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00:58:28.745 --> 00:58:31.365

and they're capable of responding to external stimuli.

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00:58:32.305 --> 00:58:35.485

So from the European Medicines Agency regulatory

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00:58:35.485 --> 00:58:37.165

perspective, a characterization

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00:58:37.165 --> 00:58:39.725

of cell population requires several characteristics

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00:58:39.745 --> 00:58:42.685

to ensure a reproducible final product.

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00:58:43.425 --> 00:58:45.045

And it is a question of the source,

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00:58:45.265 --> 00:58:47.485

the production process and the structure features.

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00:58:48.065 --> 00:58:49.085

So ideally,

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00:58:49.485 --> 00:58:53.085

a patent portfolio covering sell products should have claims

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00:58:53.275 --> 00:58:55.325

corresponding to the features of the product

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00:58:55.715 --> 00:58:57.845
that will receive the market authorization.

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00:58:58.505 --> 00:58:59.805
So you, it's important

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00:58:59.835 --> 00:59:03.165
that the claim patent claims actually mimic

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00:59:03.665 --> 00:59:05.925
and the properties that are important

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00:59:06.345 --> 00:59:09.525
for the regulatory approval

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00:59:10.345 --> 00:59:13.405
and also having that in place

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00:59:14.435 --> 00:59:17.125
will most likely make the process

1100
00:59:17.265 --> 00:59:20.445
of receiving supplementary protection certificates apart

1101
00:59:20.445 --> 00:59:24.125
and term extensions for such products easier.

1102
00:59:25.225 --> 00:59:26.245
So this is important

1103
00:59:26.305 --> 00:59:29.565
to keep in mind in when you characterize

1104
00:59:30.795 --> 00:59:31.925
cell population.

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00:59:33.385 --> 00:59:35.005
So to summarize

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00:59:36.795 --> 00:59:39.485

this is a very quickly developing field

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00:59:39.905 --> 00:59:41.725

and with a great market potential,

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00:59:41.825 --> 00:59:44.605

but the cost associated are very, very high.

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00:59:45.385 --> 00:59:47.605

And there are inherent issues with the technology

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00:59:47.655 --> 00:59:51.445

where standard patentings strategies are challenged.

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00:59:52.185 --> 00:59:54.805

So cell therapy products may be autologous or allogeneic,

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00:59:55.105 --> 00:59:57.845

and they require different approaches to patenting

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00:59:58.945 --> 01:00:02.805
and defining cell populations of cell therapy products that

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01:00:02.865 --> 01:00:05.645
requires very careful consideration.

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01:00:06.065 --> 01:00:09.845
But the accessory product for cell therapies

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01:00:10.025 --> 01:00:13.725
are most often easier to protect, such as the vectors used

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01:00:13.725 --> 01:00:16.925
for gene delivery

1118
01:00:17.865 --> 01:00:20.885
and patents relating to methods within this area, such

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01:00:20.885 --> 01:00:22.365

as methods of production as well

1120
01:00:22.365 --> 01:00:23.885
as treatment regimens are likely

1121
01:00:23.905 --> 01:00:28.085
to play quite a large role in patent portfolios where

1122
01:00:28.115 --> 01:00:30.565
product as such is hard to protect.

1123
01:00:31.305 --> 01:00:32.645
And is this a very important

1124
01:00:32.665 --> 01:00:34.685
to align the patenting strategies

1125
01:00:34.685 --> 01:00:38.605
and the portfolio with the regulatory aspects and SPC

1126

01:00:38.825 --> 01:00:40.245
or requirements.

1127
01:00:41.385 --> 01:00:46.045
So as a comment here on a second

1128
01:00:46.545 --> 01:00:49.285
and further medical use is the possibility

1129
01:00:49.385 --> 01:00:51.965
of getting protection for such inventions.

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01:00:52.075 --> 01:00:56.125
It's also important to be aware of within the at ATMP field.

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01:00:58.105 --> 01:01:01.645
So if your invention is a medical use of a known product,

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01:01:01.865 --> 01:01:04.925
it is possible to get patent protection for that as well.

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01:01:05.905 --> 01:01:08.405

Because that protection can be obtained as a second

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01:01:08.465 --> 01:01:13.245

or further medical use of product in Europe

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01:01:13.465 --> 01:01:15.645

and as a therapeutic method in the US.

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01:01:16.345 --> 01:01:18.925

So the differences between jurisdictions in

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01:01:19.025 --> 01:01:22.845

how patent claims such inventions are to be worded and

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01:01:22.845 --> 01:01:26.325

therefore the scope of protection also is different from

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01:01:26.325 --> 01:01:28.685

different in different jurisdictions.

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01:01:29.865 --> 01:01:34.045

However, I would just look at the European case.

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01:01:34.305 --> 01:01:37.045

So according to European practice, when a substance

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01:01:37.045 --> 01:01:40.685

or composition is already known, it may be patentable

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01:01:41.905 --> 01:01:43.165

if that known substance

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01:01:43.165 --> 01:01:45.885

or composition was not previously disclosed

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01:01:46.265 --> 01:01:49.645

for use in a therapeutic or diagnostic method as such.

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01:01:50.265 --> 01:01:54.325

So that could be, if it's not known

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01:01:54.465 --> 01:01:57.765
for any, uh, diagnostic therapeutic use, then you can obtain

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01:01:57.765 --> 01:02:00.165
what we call first medical use protection.

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01:02:00.165 --> 01:02:03.525
However if it is known for a different indication,

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01:02:04.985 --> 01:02:09.005
uh, second or further medical uses can be protected.

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01:02:10.105 --> 01:02:14.285
And further medical uses can also relate to,

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01:02:15.145 --> 01:02:18.885
new patient populations, new treatment regimens

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01:02:19.585 --> 01:02:21.005
for the same indication.

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01:02:22.705 --> 01:02:26.525
And as I said, this type of protection is available,

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01:02:27.025 --> 01:02:30.365
in many countries over the world,

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01:02:30.465 --> 01:02:33.325
but not in all, for example, not in India.

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01:02:34.105 --> 01:02:37.685
And the claims are drafted in different ways

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01:02:38.225 --> 01:02:40.085
in different countries, which means

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01:02:40.675 --> 01:02:44.965
that the protection scope is somewhat different.

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01:02:45.795 --> 01:02:50.765

However, it is important to realize here that these,

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01:02:50.945 --> 01:02:54.485

and this is not protection for products as such.

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01:02:54.505 --> 01:02:57.645

So second medical use claims, they are very important

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01:02:58.265 --> 01:03:02.685

for therapeutics and in general, such claims.

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01:03:02.945 --> 01:03:05.845

The second medical use claims, they provide the protection

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01:03:06.225 --> 01:03:07.685

for originator companies

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01:03:07.705 --> 01:03:10.685

to recoup research investments into therapeutic advances

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01:03:11.025 --> 01:03:12.285

of known entities.

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01:03:12.985 --> 01:03:16.885

So there's not worldwide consensus on how those claims are

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01:03:16.885 --> 01:03:18.565

to be drafted

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01:03:18.955 --> 01:03:23.005

because local law have different requirements.

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01:03:23.465 --> 01:03:26.965

But it's important to note that the product, the compound

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01:03:27.065 --> 01:03:30.085

or the the product as such is not protected.

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01:03:30.795 --> 01:03:34.045

Instead, the medical use claims primarily serve

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01:03:34.065 --> 01:03:36.765
to prevent others from marketing the product

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01:03:36.985 --> 01:03:38.845
for a specific medical indication.

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01:03:40.425 --> 01:03:41.885
So they primarily serve

1177
01:03:41.945 --> 01:03:45.845
to prevent a third party from marketing the product for

1178
01:03:46.545 --> 01:03:47.565
the protected indication.

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01:03:48.745 --> 01:03:52.045
And we know for example, that

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01:03:52.825 --> 01:03:54.805
skinny labeling is used

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01:03:55.025 --> 01:03:57.325
to circumvent this type of protection.

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01:03:57.385 --> 01:04:02.125
So wherein, on the

1183
01:04:03.175 --> 01:04:06.245
label of the product,

1184
01:04:06.905 --> 01:04:11.525
the on the product information,

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01:04:12.225 --> 01:04:14.845
this excludes referring

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01:04:14.845 --> 01:04:17.405
to indications which are protected by patents.

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01:04:17.505 --> 01:04:22.125

So there is, while these may be very important

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01:04:23.945 --> 01:04:27.205

rights, they are not have a narrower protection scope

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01:04:27.515 --> 01:04:31.125

then product patterns.

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01:04:34.785 --> 01:04:38.805

So we, as a last couple of slides, I would like

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01:04:38.805 --> 01:04:41.645

to talk about IP as a business tool

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01:04:41.645 --> 01:04:44.045

because this is very important.

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01:04:44.265 --> 01:04:45.605

We create IP,

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01:04:45.745 --> 01:04:48.485
but we IP is there in order

1195
01:04:48.585 --> 01:04:51.325
to promote business transactions.

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01:04:52.265 --> 01:04:56.605
And having IP without knowing how it

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01:04:57.375 --> 01:04:58.645
works within the business

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01:04:58.705 --> 01:05:01.285
and how it adds value to the business is

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01:05:03.845 --> 01:05:07.085
pretty much, so to say, a waste of money.

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01:05:08.105 --> 01:05:11.845

So it is that to strengthen your business position

1201
01:05:11.945 --> 01:05:15.285
by controlling your relations with others, just competitors,

1202
01:05:15.605 --> 01:05:17.485
suppliers, collaborators and customers.

1203
01:05:18.505 --> 01:05:19.925
And it's there

1204
01:05:20.145 --> 01:05:23.165
to block your competitors from your market segment.

1205
01:05:23.825 --> 01:05:28.605
But you have to remember that you are not navigating

1206
01:05:28.905 --> 01:05:31.845
alone in this patent landscape.

1207

01:05:31.845 --> 01:05:35.245
There are other actors and you have to stay clear

1208
01:05:35.465 --> 01:05:36.525
of their rights.

1209
01:05:36.625 --> 01:05:38.925
So you need to ensure that your freedom to operate

1210
01:05:38.945 --> 01:05:43.285
and that your activities do not conflict

1211
01:05:43.285 --> 01:05:44.965
with somebody else's rights.

1212
01:05:45.785 --> 01:05:46.005

1213
01:05:51.825 --> 01:05:54.365
And I just want to urge you

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01:05:54.425 --> 01:05:57.765

to consider your invention from a business perspective.

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01:05:58.775 --> 01:06:01.205

These are business tools, like I said,

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01:06:01.425 --> 01:06:02.525

and it's important

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01:06:02.585 --> 01:06:04.805

to align your patterns with your business model.

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01:06:05.265 --> 01:06:08.405

So consider how are you planning on making money

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01:06:08.905 --> 01:06:11.845

and how is

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01:06:11.845 --> 01:06:14.165

that patent right gonna help you in that.

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01:06:14.225 --> 01:06:15.685

Are you going to attract investment?

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01:06:15.905 --> 01:06:18.685

Are you gonna develop your product yourself?

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01:06:18.745 --> 01:06:20.245

Are you seeking partnerships?

1224

01:06:20.825 --> 01:06:24.525

Are you going to take the product

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01:06:24.585 --> 01:06:25.765

to the clinic yourself?

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01:06:25.865 --> 01:06:27.485

Are you planning to license it to others?

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01:06:28.465 --> 01:06:32.045

And of course, consider the business

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01:06:32.195 --> 01:06:34.165

environment in your technology.

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01:06:34.345 --> 01:06:37.405

Is it competitive? How are your competitors?

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01:06:37.515 --> 01:06:40.245

What are they doing? How does your technology differ?

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01:06:40.505 --> 01:06:43.205

And are there any third party rights

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01:06:43.205 --> 01:06:44.285

that can hinder your plans?

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01:06:44.425 --> 01:06:45.925

Do you have freedom to operate?

1234

01:06:47.025 --> 01:06:50.285
So just as a last point here,

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01:06:51.315 --> 01:06:54.645
when you're entering into a collaboration

1236
01:06:54.825 --> 01:06:59.205
or, a business, a relationship,

1237
01:07:01.235 --> 01:07:02.765
make sure that

1238
01:07:03.465 --> 01:07:05.925
before signing an agreement, you do not say too much.

1239
01:07:06.705 --> 01:07:10.685
Make sure that you file a patent application prior

1240
01:07:10.865 --> 01:07:14.965
to disclosing information in order to ensure

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01:07:14.965 --> 01:07:16.125

that you're not being scooped

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01:07:16.125 --> 01:07:17.725

of your invention, of your technology.

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01:07:18.185 --> 01:07:19.685

And define your background rights.

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01:07:19.715 --> 01:07:22.045

What are you bringing to the table from your end

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01:07:22.155 --> 01:07:23.285

into the collaboration?

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01:07:24.025 --> 01:07:26.125

And also make sure that you set out the

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01:07:26.125 --> 01:07:27.445

terms of the collaboration.

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01:07:28.225 --> 01:07:29.805

Are there any.

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01:07:32.585 --> 01:07:35.605

Who decides what, who does what within the collaboration?

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01:07:36.145 --> 01:07:40.525

Um, who has a responsibility for pursuing infringement?

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01:07:40.545 --> 01:07:42.805

who has a responsibility for patent prosecution?

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01:07:44.465 --> 01:07:45.845

And also consider the future,

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01:07:46.755 --> 01:07:50.445

what happens when you develop something together within this

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01:07:50.765 --> 01:07:53.405

collaboration? who owns the right

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01:07:53.705 --> 01:07:55.245

to further developments?

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01:07:55.945 --> 01:07:58.765

who owns what if the agreement is terminated?

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01:07:58.905 --> 01:08:00.565

So these are very important aspects

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01:08:00.565 --> 01:08:02.325

to keep in mind when you're entering

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01:08:02.515 --> 01:08:04.645

into business relationships.

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01:08:08.665 --> 01:08:11.565

So thank you so much for listening to this talk.

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01:08:11.805 --> 01:08:13.965
I hope it has been interesting

1262
01:08:14.105 --> 01:08:15.645
and that you have learned something.

1263
01:08:15.645 --> 01:08:18.725
Please look over the information that I have, including

1264
01:08:18.785 --> 01:08:20.245
as background reading material.

1265
01:08:20.665 --> 01:08:23.485
And again please feel free

1266
01:08:23.485 --> 01:08:26.565
to reach out if you have any questions and comments.

1267
01:08:26.735 --> 01:08:27.525
Thank you so much.