



DRAFT of Next Variant of International Arbitration: Life Sciences *

Summary

*** Please note that this summary of the panel was AI-generated and therefore has not been fully vetted for accuracy.**

The session at Washington Arbitration Week focused on the intersection of life sciences and international arbitration, highlighting the growing importance of this field in arbitration practice. Moderated by Patrick Pierce, a leader in international arbitration at Allen & Overy, the panel included experts Brent M. Antie, Dr. Peter Rankin, and Imani Chee Chicot, who brought diverse perspectives from government relations, economic analysis, and international law.

The discussion underscored the increasing relevance of life sciences in international arbitration, with approximately 25% of current ICC cases involving intellectual property (IP) issues. The panelists emphasized the critical role of IP in life sciences, noting that effective protection of trade secrets and patents is essential for fostering innovation and securing investments in the sector. They explored the complexities of arbitration clauses, particularly regarding IP disputes, which often lead to legal ambiguities and challenges in enforcement.

Brent Antie discussed the regulatory landscape, emphasizing the need for predictability in the approval processes for life sciences products, especially following the COVID-19 pandemic. He highlighted the U.S. government's efforts to bolster domestic manufacturing and the implications of recent legislation on pricing and regulatory practices.

Dr. Peter Rankin focused on the valuation of early-stage intellectual property and the challenges of quantifying damages in disputes. He pointed out that collaboration agreements often contain effort clauses that can lead to disputes over performance expectations, particularly in the context of the highly regulated life sciences environment.

Imani Chee Chicot addressed strategic considerations for arbitration in life sciences, highlighting the importance of drafting clear dispute resolution clauses that account for the unique challenges of IP-related disputes. She also noted the potential for investment treaty protection to safeguard against state actions that could undermine IP rights.

The panel concluded with a discussion on the implications of changing economic conditions



on investment in life sciences, noting that tighter financial environments often lead to an increase in disputes as companies seek to protect their interests.

Overall, the session provided valuable insights into the evolving landscape of life sciences arbitration, emphasizing the need for practitioners to stay informed about regulatory developments and to adopt proactive strategies in contract drafting and dispute resolution.

Authors

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Topics

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Category

WAW

Full Transcript

00:00:02

Washington arbitration week. I will

00:00:05

make this very, very short

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apart from saying thank you

00:00:08

very much to Allen &

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every and and the everyone

00:00:11

that is sitting with me,

00:00:12

I must say those things

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about our moderator. This is

00:00:18
a panel that was a

00:00:19
visit first time that we

00:00:21
have a paddle in life

00:00:21
and Sciences in at Washington

00:00:24
arbitration week. And this is

00:00:25
mainly because of fox Patrick

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Pierce sales and Catering Flores

00:00:31
initiative. We we we basically

00:00:36
thought we know what would

00:00:37
be Innovative. What would be

00:00:39
important in terms of growth

00:00:42
of arbitration in a specific

00:00:44



field? And there you go,

00:00:46

they raise their hand. I

00:00:48

said, well, we must have

00:00:49

a panel on light and

00:00:51

Sciences because of the, the

00:00:54

steps and the growth in

00:00:57

in general, International commercial arbitration.

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But not only that investor

00:01:01

arbitration Etc. Simply allow me

00:01:04

to say that. Patrick is

00:01:06

the leader of international arbitration

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at Alan. The warrior ovary

00:01:14

in. In that Washington d.c.,

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he has extensive experience, representing

00:01:18

parties international disputes and providing

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strategic advice on asset protection,

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Global investment and Commercial contract.

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He served importantly in the

00:01:29

US, state department for nearly

00:01:32

a decade working on economic

00:01:35

and natural resources, diplomacy and

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departed and departed as the

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chief of investment arbitration. In

00:01:45

addition to his representations, Patrick

00:01:48

was on a drafting committee

00:01:52

for the revision of international

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Court of arbitration rules. And

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led the negotiations with several

00:01:58

bilateral or multilateral treaty. He

00:02:00

advised on the negotiations of

00:02:02

the investment, Provisions in the

00:02:04

trans-pacific partnership, TPP and the

00:02:07

transatlantic trade and investment partnership.

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And the US China, bilateral

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investment treaty, he has received

00:02:15

several Awards and serves as

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served on multiple boards. He's

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also an Adjunct professor at

00:02:23

Georgetown. He has a being

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in several or he's part

00:02:28

of several arbitration centers. And

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that lately has also being

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involved in a various ever

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presentations related to thank you

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and with you or moderate.

00:02:42

Thanks, Jose. Antonio, I think

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this is working. Welcome to

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everyone in the room and

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online. I really appreciate you

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turning in the Monday after

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Thanksgiving. And for those of

00:02:55

you watching it in a

00:02:55



recording, it is the Monday

00:02:57

after Thanksgiving, where we are

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and we're very grateful for

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everyone to be. Here. We

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have a a what we

00:03:04

hope is a pretty exciting

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hour and 10 minutes or

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so, for you today we're

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going to be talking about

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life sciences and for those

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of you who are a

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little bit confused or questioning,

00:03:17

what, what is, what our

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life sciences, what is life

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sciences? How does it work?

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International arbitration. That's the purpose

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of the panel. So thank

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you, Jose Antonio for your

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invitation to us. All Washington

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arbitration week has become a

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can't-miss moments on the arbitral

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calendar and your willingness to

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pursue new areas that have

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not been discussed. Has is

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very much appreciated in life

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sciences is one of those.

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He mentioned Jose Antonio mentioned

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growth. The reason we're here

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is because we see Life

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Sciences as a particularly important

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growth area and international arbitration

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something on the order of,

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we are just starting to

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get some statistics on this

00:03:59

around, a quarter of cases,

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currently in that the ICC,

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for example, relate to some

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IP issues. So, that that's

00:04:09

pretty significant, that a quarter

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of the cases right now,

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have IP a Jason or

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IP related issues. I think

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that is only going to

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continue. So we're going to

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talk about it. What is

00:04:20

it? What are the rules?

00:04:21

Why does it matter how

00:04:23

to clients Implement them in

00:04:25

their deals? And how does

00:04:26

it work in arbitration? And

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with us, we have the

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experts as Jose Antonio said,

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Washington arbitration week likes to

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call on the experts and

00:04:36

now we have them. So,

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to my immediate right is

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Brent them. Auntie, he serves

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as the co-head of Life

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Sciences at at BGR group.

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He represents clients, particularly in

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life sciences, companies to help

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them achieve their objectives. With

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regard, to the federal government,

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to US federal government. He's

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worked for Senator Warner, representative

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Li Li, he clerked for

00:05:00

judge Hilton and has been

00:05:03

counseled to the house committee

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on Energy and Commerce, where

00:05:06

he had responsibilities over Food

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and Drug related issues. He

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oversaw the empty enactment of

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several laws, which I don't

00:05:14

fully understand, but I will

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read them. Medical user fee

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act, the project, bioshield Act,

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and the reauthorization than this

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one, I do know about

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best Pharmaceuticals for children Act

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and the prescription drug user

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free act. The Padova pdufa

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is also a senior vice

00:05:35

president for the federal government

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relations at the biotechnology industry

00:05:39

organization, which has the great

00:05:42

acronym bio, where he successfully

00:05:44

oversaw the enactment of priority,

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legislation more therapeutic project, Discovery

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tax, credit liability protections for

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bioterrorist in pandemic. Countermeasures to

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reauthorization of the other law

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that he did. The producer,

00:05:58

does anyone call it that?

00:06:00

Nailed it. That's, that's some

00:06:04

acronym training, including important reforms

00:06:06

of the accelerated approval pathway

00:06:08

at the FDA patent reform

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and 21st century cures initiative.

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So talking to his right

00:06:16

is Dr. Peter Rankin, he's

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a PhD Economist and life's

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and chairs, the life sciences.

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Practice at Charles River Associates

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for more than 20 years,

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you've provided economic analysis and

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opinion involving disputes involving pharmaceutical

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biotechnology and medical device manufacturers.

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He is offered public and

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proprietary policy evaluation projects involving

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Health Care reform. Reimbursement, methodologies

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antitrust, exemption research and development

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initiatives and research productivity. These

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are these are maps. That's

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that's part. And parcel of

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Life Sciences, big words, he's

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served as an expert in

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litigation and arbitration which is

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how we know him. He's

00:07:00

testified many times before Congress.

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In arbitral disputes, he's often

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retained to access to access

00:07:06

the breakdown development of commercial

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and commercialization agreement. And he

00:07:11

has analyzed scores of agreements

00:07:14

in the Life Sciences industry.

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That's what he'll be talking

00:07:17

about today and Hill. Discuss

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those terms and what they

00:07:20

tend to require in international

00:07:22

arbitration and to his right

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is a woman who probably

00:07:27

needs no introduction to those

00:07:28

of us in Washington, money

00:07:30

cheek, Chicot, chairs, Covington's, International

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arbitration, practice and handles a

00:07:35

wide variety of international commercial

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and investment, treaty matters. She

00:07:40

also most impressed, most importantly,

00:07:42

I also, most importantly, serves

00:07:45

as counsel to Ukraine at

00:07:47

the international court of justice

00:07:47

where she just received a

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very favorable ruling on provisional

00:07:52



measures and is really doing

00:07:54

international law, a great service

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and we thank her for

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that. Imani is experience with

00:07:59

life sciences disputes. However, dates

00:08:02

back to her time, as

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associate counsel at the office

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of the ustr, the US

00:08:06

trade representative since joining Covington

00:08:08

where she's, of course a

00:08:09

partner, she has handled high-profile

00:08:12

investment treaty disputes and including

00:08:14

probably the most famous pharmaceutical

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dispute in. STS v e

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l, i Lilly versus Canada

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case, where she represented, Eli

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Lilly and has successfully arbitrated

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disputes under Life Sciences agreements,

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including a 1.8 billion dollar

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trade secret claim, which will

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hopefully hear a little bit

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more about. She is among

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many boards and Association member

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of the Council on Foreign

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Relations and is on the

00:08:42

dispute settlement. Roster for the

00:08:44



Central, American Free, Trade Agreement

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and the Korean Us free

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trade agreement. So, Experts, if

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you didn't get that, that's

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the headline. So let's let's

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start with, with, Brent, Brent.

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I wonder if you could

00:08:58

kind of set the scene

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for us, what, what, what

00:09:01

are the laws? What are

00:09:03

we talking about? How does

00:09:04

it relate to two US

00:09:05

regulatory, oversight, and kind of

00:09:09



will start peeling, the onion

00:09:10

about how those disputes happen.

00:09:11

Sure. Thank you very much

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and I hope you all

00:09:14

can hear me and I

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hope this is a very

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informal setting, which I appreciate

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I would say, let's have

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a good conversation, give me

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a squirrel. Then what did

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I bring notes to a

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conversation? And I would just

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know that I frequently do

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that with my wife is

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well I'm about to head

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to the health and Life

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Sciences. Practice at the B&G

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are grouped. We have the

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Good Fortune of representing a

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number of innovative good drug

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biologic, Medical Technology medical device

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manufacturers. We have some insight

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into what they are looking

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for generally and that is

00:09:48

of course, predictability and fair.

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In the regulation of their

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products baleen in but they

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work with Democrats and Republicans

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to ensure the predictability. It

00:10:00

is a major factor in

00:10:01

also just ensuring that they

00:10:03

know what to expect when

00:10:03

they approached the FDA. I

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am a former FDA council

00:10:08

at the end, house Energy

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and Commerce. I have a

00:10:10

different take and viewpoint but

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I think it's pertinent to

00:10:13

the discussion that we're going

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to be having today about

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International arbitration. Because what we've

00:10:20

been seeing recently is the

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push on the behalf of

00:10:23

many lawmakers to have and

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and and to have things

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more or less internationally focused

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and more domestically focused in

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terms of our supply chain,

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there was a tremendous re-examination

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of the supply chain as

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we headed into the pandemic,

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there have been voices out

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there for some time who

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ever heard of a look

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at the supply chain, but

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I tell you a once

00:10:49

in a hundred years, pandemic,

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Really spur the interest of

00:10:53

folks. As we have this

00:10:56

conversation I can tell you

00:10:57

generally. Another thing that life

00:10:59

sciences companies care deeply about

00:11:01

is a resilient supply chain

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but also a redundant supply

00:11:05

chain because whether it be

00:11:07



a pandemic or a natural

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disaster or just a breakdown

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at a facility, which is

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of great importance to production

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of a certain therapeutic or

00:11:17

vaccine. You need to have

00:11:19

supply chain supply chain with

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many different components to it.

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So, the notion of, well,

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let's just bring everything back

00:11:28

to the United States, doesn't

00:11:30

make sense because you need

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to be located in very

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many different places to ensure

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resilience and redundancy. Now, that's

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not to say that we

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shouldn't be trying to do

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more in the United States.

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Because one thing the pandemic

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has shown us, is there

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a number of components to

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Therapeutics and vaccines and medical

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devices which were manufactured elsewhere?

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Really at endemic in a

00:11:53

create shortages things that we

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do not want. But we

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know for a fact that

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the B Administration has taken

00:12:00

resiliency of the supply chain

00:12:03

as a top priority, one

00:12:06

of their first executive orders

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early on in the bottom

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presidency commanded, a number of

00:12:12

different agencies and departments to

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give a look at the

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supply chain. It was America

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Supply chains was the name

00:12:19

of the executive order and

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HHS was told to look

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at pharmaceutical and medical device

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and vaccine resiliency, which they

00:12:28

subsequently did. And earlier this

00:12:31

year, they reported back and

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they talk about the types

00:12:36

of Investments, which have been

00:12:37

made during the pandemic of

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more than four billion dollars

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to help the manufacturing of,

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you know, Whether it be

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API, active, pharmaceutical ingredients ingredients,

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for key, starting materials up,

00:12:53

to finish dosage and she

00:12:56



felt formulations, they wanted to

00:13:00

have more of that being

00:13:01

done in the United States.

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And they did put out

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billions of dollars. And frankly,

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they were pretty wise Investments,

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so that has been going

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on a dish sling. Earlier

00:13:15

this year the Biden Administration

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put out an executive order,

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I was focused in some

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part of his entitled advancing

00:13:26

biotechnology and biomedical fractured executive

00:13:29



order. And what they did

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is they commanded White House

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to have a series of

00:13:35

meetings between industry and Regulators

00:13:39

to talk about what more

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could be done. And as

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part of this executive order,

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they told the Department of

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Defense to spend another billion

00:13:51

dollars. I believe it is.

00:13:52

Yeah, to catalyze the establishment

00:13:54

of the best domestic and

00:13:56

bio industrial manufacturing base. So

00:13:59



all of this money is

00:14:00

going out the door to

00:14:02

bolster domestic manufacturing again, trying

00:14:07

to bring things back to

00:14:09

the United States. At the

00:14:11

same time, they're concerned regulatory

00:14:12

tools, that FDA has been

00:14:14

employing to try to address

00:14:16

shortages and try to encourage

00:14:19

domestic manufacturer, one of which

00:14:22

has advanced manufacturing technology State

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have an office at the

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FDA, the emerging Technologies program,

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which is looking at these

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Technologies, which make it cheaper

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to end and easier. Easier

00:14:35

cheaper to manufacture it, manufacturer

00:14:38

in the United States things

00:14:41

like continuous manufacturing. 3D manufacturing

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certain types of other platform

00:14:47

Technologies which which can provide

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for more predictability and more

00:14:52

round-the-clock manufacturer to address drug

00:14:55

shortages and having that being

00:14:57

done in the United States.

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So there has been an

00:15:00



all of government approach to

00:15:02

ensuring to the greatest extent

00:15:04

practicable. At the same time

00:15:07

to Congress has been spending

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a heck of a lot

00:15:09

of time. Focused on this

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issue. And at the beginning

00:15:13

of the pandemic, there were

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some really I use a

00:15:17

technical term crazy ideas which

00:15:19

were being proposed. Such as

00:15:22

you know, you can't sell

00:15:24

any United States. Unless all

00:15:26



the components in the Finish

00:15:27

dosage forms Etc, are being

00:15:29

made in the United States.

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You can't sell to know

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the largest purchaser of drugs

00:15:33

in the united states. Is

00:15:34

medical technology and alike. How

00:15:37

are user at least is

00:15:39

federal government through the Medicare

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and Medicaid Program, VA Health

00:15:43

defense, Health at cetera and

00:15:47

some were saying while you

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can't government can't purchase unless

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it's made that's entirely impracticable

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and fortunately ideas like that

00:15:54

or not or not, ultimately

00:15:56

pursued but instead As we

00:15:59

are in a, you know,

00:16:00

that roofer year there is

00:16:01

a user-fee access medical devices,

00:16:03

prescription drug excetera, they have

00:16:06

been taking efforts to encourage

00:16:09

again, domestic manufacturer Senators, Murray

00:16:13

and Senator Burr. Have a

00:16:15

bill which is under consideration

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right now. Which would empower.

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The federal government to set

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aside certain manufacturing rights in

00:16:25

the case of a pandemic

00:16:26

it's called warm Ace manufacturing.

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That's under consideration right now.

00:16:32

And again on both the

00:16:34

house and the Senate side

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there is a consideration of

00:16:36

a pilot program on Advanced

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Manufacturing Technologies. We're in for

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the first time manufacturers were

00:16:45

would be able to seek

00:16:47

a designation that their technology

00:16:48



itself divorce from the consideration

00:16:51

of an application but rather

00:16:53

their technology could be designated

00:16:55

so that in the future

00:16:56

other third parties. Your license

00:16:59

with that, they license with

00:17:00

can use that technology and

00:17:02

rely upon that technology and

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FDA would give priority to

00:17:05

the review of the product

00:17:06

made with that technology, all

00:17:08

under consideration right now. But

00:17:10

I guess the punchline which

00:17:12



and I've been repetitive, so

00:17:13
you should get it is

00:17:14
the fact that while not

00:17:16
on International arbitration itself impacting.

00:17:19
It is the desire that

00:17:20
many folks, many see how

00:17:22
many lawmakers want to bring

00:17:24
things back to the United

00:17:25
States. Not at the exclusion

00:17:27
of international, but if future

00:17:30
manufacturing capacity, thanks that's. That's

00:17:33
exceptionally helpful and I didn't

00:17:36
realize it was a new

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four-year. Now, he's now we

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know and we can we

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can roll that out to

00:17:41

our clients. I mean, I

00:17:42

do think just kind of

00:17:43

continued to contextualize this. It

00:17:46

is exceptionally important that as

00:17:47

lawyers we do more of

00:17:49

this, where we get a

00:17:50

sense of what what the

00:17:51

kind of industry and the

00:17:53

regulatory oversight of that industry

00:17:55

is providing for so that

00:17:58



we can anticipate As a

00:17:59

t are professionals disputes and

00:18:01

help our clients resolve those

00:18:03

disputes before they arise. Right?

00:18:05

I mean, that's when we

00:18:06

show value is arbitration practitioners,

00:18:08

it's it's in that it's

00:18:09

keeping disputes from courts and

00:18:11

end in ensuring, we do

00:18:13

our best to resolve those

00:18:14

disputes before they happen. So,

00:18:16

that's very helpful. I have

00:18:16

lots of questions about supply

00:18:18



chain, redundancies and things, but

00:18:20

we'll save those for after

00:18:22

we hear from Peter, Peter

00:18:25

is going to tell us

00:18:26

in a new four-year with

00:18:27

all of this on Shoring

00:18:28

activity. How are you seeing

00:18:31

this manifest itself in in

00:18:33

deals? So as a caveat

00:18:36

life, may be the only

00:18:37

one in the room who

00:18:38

is not in the attorney.

00:18:39

I'm going to call his

00:18:40



by training. I work at

00:18:41

a consultancy and is Patrick

00:18:44

said, I lead our litigation

00:18:45

group, but I think one

00:18:47

of the things that's interesting

00:18:48

contacts is our litigation group

00:18:50

is actually the smallest piece

00:18:52

of what we do in

00:18:53

life sciences. Most of my

00:18:54

colleagues are strategy Consultants. So

00:18:57

they are retained by pharmaceutical

00:18:59

manufacturers, biotech, medical device. Diagnostics

00:19:02

to help them deal with

00:19:05



Business realities launched products, how

00:19:07

to anticipate changes that may

00:19:10

happen governmentally. We also have

00:19:13

a policy group that looks

00:19:15

at different proposed legislation and

00:19:18

works with the trade organizations,

00:19:19

like biopharma FBI p.m. a

00:19:21

2 in that context. Most

00:19:24

of my colleagues are out

00:19:25

there really wrestling with how

00:19:27

manufacturers go about bringing therapist

00:19:31

to clients. Bring devices to

00:19:32

clients, not shockingly to those

00:19:36



involved in, in in life

00:19:38

sciences the real key to

00:19:41

life science is the lifeblood

00:19:42

is innovation and finding new

00:19:45

ideas for new therapies. That's

00:19:47

where the scarcity is, is

00:19:49

an economist. That's what I

00:19:50

look for. Where's the scarcity

00:19:51

if the idea is, is

00:19:52

what can we develop into

00:19:53

a new therapy? That makes

00:19:55

intellectual property protection, critically important,

00:19:58

Trade, Secrets, patents every form

00:20:02



of intellectual property protection and

00:20:04

so In the context of

00:20:06

disputes, we see what's happening.

00:20:08

Most recently, there is a

00:20:11

real Dyer effort right now

00:20:15

to try to properly. Protect

00:20:19

in value, early-stage intellectual property,

00:20:22

even before it's a patent,

00:20:23

when it's a trade secret,

00:20:24

you have a great idea

00:20:27

for a new genetic therapy

00:20:30

but you know, you know,

00:20:32

add best if everything breaks

00:20:33



right 20 years until commercialization

00:20:36
and a lot of clinical

00:20:37
testing between now and then

00:20:38
in a lot of production

00:20:39
issues to work out. So

00:20:41
what happens if your collaboration

00:20:43
partner makes light-fingered use of

00:20:47
assets that were involved in

00:20:49
a collaboration agreement? How do

00:20:50
you value that? We know

00:20:51
and litigation, very, very difficult

00:20:53
in the context of litigation.

00:20:55
The standard for damages if

00:20:57



you are harmed is can't

00:21:00

be speculative but I'll definitely

00:21:02

we're talkin about. I pee.

00:21:04

That's, you know if it's

00:21:05

free. It's got what a

00:21:08

8% chance of ever being

00:21:09

invited and commercialize products. And

00:21:12

then you got all the

00:21:13

pricing issues to deal with.

00:21:14

There's there's a long long

00:21:15

road ahead and so courts

00:21:18

have said that, you know,

00:21:19

I feel bad for you.

00:21:20



But you can't give me

00:21:21

that at non-speculative damages amount.

00:21:23

Can you tell us what

00:21:24

light-fingered uses? It's often the

00:21:33

case that There are so

00:21:36

many different aspects developing even

00:21:38

before you get to commercializing

00:21:39

but developing a new therapeutic

00:21:41

Target that lots of different

00:21:44

parties involved and so there

00:21:46

is licensing with production specialist

00:21:49

with different types of scientists.

00:21:52

You might have to run

00:21:54



clinical trials in other countries

00:21:55

which involves sharing protocols with

00:21:58

folks who might be a

00:22:00

key opinion leaders and working.

00:22:02

You don't have relationships with

00:22:03

other manufacturers and suddenly you

00:22:05

see something that looks stunningly.

00:22:06

Like North Port O'Call being

00:22:08

run for a product that's

00:22:09

not yours. And there's a

00:22:11

slight suspicion that you may

00:22:13

have been the author of

00:22:14

that even if you would

00:22:15



have preferred not in. So,

00:22:17

you know what, we see

00:22:19

really in commercial arbitration recently

00:22:22

is kind of two themes

00:22:23

in the first is, how

00:22:24

do you protect? How do

00:22:25

you value? What kind of

00:22:26

Road marks? Can you put

00:22:28

down to Value? Early-stage IP

00:22:31

in case your Trade Secrets?

00:22:32

Wonder if you can't, To

00:22:36

a revenue stream of an

00:22:38

eventual commercialize product, what can

00:22:40



you point to? And what

00:22:41

we see in the lot

00:22:42

of contracts is looking at

00:22:43

a valuation of timeline, you

00:22:47

know? If it is the

00:22:48

case that this trade secret

00:22:50

allowed, you a six-month leak

00:22:51

in your protocol development. What

00:22:55

is that 6 months translate

00:22:56

to? And look there still

00:22:57

lots of discounting because we

00:22:59

know that saving six months

00:23:00

free stage. One doesn't mean

00:23:01



you're launching 6 months, early.

00:23:02

There's a lot of regulatory

00:23:04

development. This institute is between

00:23:05

the event and and the

00:23:09

realization, but it's a landmark.

00:23:12

There's also a fairly Viber

00:23:14

Investment Banking community. And so

00:23:16

if people are willing to

00:23:17

make bids on early-stage Research,

00:23:18

that's at least markers in

00:23:20

the environment that can be

00:23:21

looked at in terms of

00:23:22

valuing, some of that early-stage

00:23:24



technology. And often in life

00:23:28

sciences, what we go to

00:23:30

is, comprable spell, there's got

00:23:31

to be something like this.

00:23:32

Very last thing you want

00:23:39

to do, especially early on

00:23:40

Tuesday, but it's like this

00:23:41

other product. Or if you

00:23:42

look at this one, that

00:23:43

will give you a good

00:23:44

roll bar. Because the whole

00:23:45

point is that you're going

00:23:46

to have something new, you're

00:23:47



going to help patients in

00:23:48

a fundamentally novel matter. And

00:23:51

it suggested there's a benchmark.

00:23:52

Devalues you from the start.

00:23:53

The second development that we

00:23:57

seen in in the commercial

00:24:00

side, International arbitration is really,

00:24:03

I want to call wrestling

00:24:04

with efforts clauses. There are

00:24:09

hundreds thousands, many many, many

00:24:11

collaboration agreements between partners that

00:24:14

are trying to develop or

00:24:15

commercialize products and usually, these

00:24:19



contracts require effort. I'm licensing.

00:24:24

My idea to you because

00:24:26

you got that the manufacturing

00:24:28

wherewithal to, to get it

00:24:29

where it needs to be

00:24:30

until I'm entrusting you to

00:24:32

bring that product through the

00:24:34

through the development process. I

00:24:37

don't know exactly what that

00:24:38

is going to entail and

00:24:40

you might have some idea

00:24:41

but you don't know exactly.

00:24:42

It's a new therapy. We

00:24:44



need to see how the

00:24:44

clinicals come in. And so

00:24:46

what the contracts need is

00:24:47

some mechanism by which to

00:24:49

make sure that our interests

00:24:50

are aligned and that you're

00:24:52

doing your job. And so

00:24:54

typically, there is an effort

00:24:55

squash in these and there's

00:24:57

all sorts of different phrases

00:24:58

diligent efforts, best efforts, commercially,

00:25:00

reasonable effort, something to guide

00:25:03

and to guarantee that the

00:25:05



right amount of focus is

00:25:07

going to be put on

00:25:08

a developmental Target. The problem

00:25:10

is, as we know in

00:25:11

life sciences, most ideas fail,

00:25:14

right? They don't make it

00:25:15

through, clinicals the ones that

00:25:17

do off and don't live

00:25:19

up to their commercial expectations.

00:25:20

And so at the end

00:25:21

in hindsight, you might say,

00:25:23

well, this isn't what I

00:25:24

thought I was going to

00:25:24



get is that because of

00:25:26

a characteristics of the drug,

00:25:28

or is that? Because my

00:25:29

Development Department, mishandled something along

00:25:31

the way. And with genomics

00:25:35

with biologics Gene therapies, it

00:25:39

seems like there's inevitably more

00:25:41

and more people at the

00:25:42

party. Everybody bring a little

00:25:43

peace and so if things

00:25:44

don't work exactly the expectations,

00:25:46

there's much more conflict about

00:25:49

whether or not people did

00:25:51



what they ought to have

00:25:51

done how long the way.

00:25:52

We're also learning in the

00:25:55

context of international arbitration, some

00:25:56

national legal systems have a

00:25:59

deep history and efforts Clauses

00:26:01

and phrases and some have

00:26:02

none. And so Contracting parties

00:26:05

come from asymmetric backgrounds and

00:26:08

a phrase like best efforts,

00:26:09

might mean something very particular

00:26:11

to someone from the UK

00:26:14

or America and mean nothing

00:26:15



other than two words hooked

00:26:16

together to someone from France.

00:26:17

And so we seen some

00:26:20

conflicts arise from a simple

00:26:22

definition that didn't have the

00:26:24

foundation and I shouldn't we

00:26:27

talk sometimes about physician induced

00:26:29

him and I shouldn't bad

00:26:31

mouth. I meant. I am

00:26:33

an expert will retain to

00:26:34

come in and kind of

00:26:35

address these ambiguities, these vagaries

00:26:38

from the contracts. But there

00:26:40



are some times and some

00:26:41

odd breakdown at the start,

00:26:43

just because the language is

00:26:44

different. Recently, there's been a

00:26:47

couple of additional developments have

00:26:49

put extra emphasis on efforts

00:26:52

are extra stress. The first,

00:26:54

which Brent probably can tell

00:26:55

you much more about that

00:26:56

than I can. Is these

00:26:58

contracts are signed years in

00:27:00

advance and things change. Most

00:27:03

recently in the United States,

00:27:04



we have the inflation. We're

00:27:05

not going to act, which

00:27:07

passed with surprisingly, little Fanfare

00:27:09

attention once, but has massive

00:27:12

implications for pharmaceutical pricing in

00:27:14

the United States and massive

00:27:16

implications in a way that

00:27:17

isn't quite yet to find.

00:27:19

We don't know what specific

00:27:21

drugs are going to be

00:27:22

targeted for Price negotiations with

00:27:24

Medicare. We don't know how

00:27:26

that's going to affect other

00:27:27



products and a therapeutic class.

00:27:28

And we don't know how

00:27:30

a party operating under a,

00:27:32

you know, best efforts Clause,

00:27:34

2 price of product. Now,

00:27:35

has to redo the calculus

00:27:38

for fear of being swept

00:27:40

up in the IRS, changes

00:27:41

to the, to the pharmaceutical

00:27:42

pricing. We also have had

00:27:45

recent run-ins with the public

00:27:48

policy considerations, not particular policies,

00:27:50

but with an in licensing

00:27:52



manufacturer who said we don't

00:27:54

ever want to have the

00:27:56

most expensive therapy in a

00:27:58

therapeutic class as a company.

00:28:00

That's just a position. We

00:28:01

want to take a partner

00:28:06

licensing, a product to them

00:28:08

want anything other than profit,

00:28:10

maximization that partner just wants

00:28:12

the revenue. They don't really

00:28:13

care about the corporate reputation

00:28:15

or the policy stance being

00:28:16

taken by. The unlicensed are

00:28:18



And finally, the, what what

00:28:21

we see a lot in

00:28:22

the biotech world is what

00:28:23

they called. Bayou bucks, big

00:28:25

deals with lots and lots

00:28:27

of value. I just signed

00:28:29

a billion dollar contract and

00:28:32

950 million of Addison. Milestones

00:28:35

that know, the stars have

00:28:37

two perfectly aligned to do

00:28:39

to come to fruition. Does

00:28:42

the existence of Milestones imply?

00:28:44

The need to pursue them.

00:28:47



Or is it commercially reasonable

00:28:49

for an unlicensed? Or look

00:28:50

at that. Milestone say, that's

00:28:51

crazy. That's, that's, that's outside

00:28:54

the bounds of what we

00:28:55

would typically do for a

00:28:56

product like this. And so,

00:28:58

if it happens, we'll meet

00:28:59

the Milestone, but we don't

00:29:00

put any special effort into

00:29:02

achieving the milestone. Switching gears

00:29:05

quickly to the investor Stateside

00:29:08

Lifesciences hasn't really been. We

00:29:10



have notable cases and I

00:29:12

don't want to steal my

00:29:13

thunder but there are other

00:29:16

Industries I have been more

00:29:17

vibrantly at the center &

00:29:18

Event Center State arbitrations. We've

00:29:21

had our big hits, there's

00:29:22

probably about 20 cases since

00:29:25

2012 in Pharmaceuticals are pharmaceutical

00:29:27

manufacturer. We are right for

00:29:31

these kind of disputes right?

00:29:32

Pharmaceuticals biotech medical devices have

00:29:34

very high-priced cost margin. They

00:29:37



have a lot of development

00:29:39

costs. And so by the

00:29:40

time you have a product

00:29:41

everything's invested and that makes

00:29:44

potential opportunistic activity that our

00:29:47

Behavior by States, more likely,

00:29:50

There are two particular factors

00:29:52

that make us think we're

00:29:53

going to see more investor-state

00:29:54

action here. The first is

00:29:56

the patent regime scrutiny of

00:29:58

state seat products at lower

00:30:00

cost. I don't want to

00:30:03



dwell, we've heard a lot

00:30:04

about the pandemic but this

00:30:06

is the category into which

00:30:07

compulsory licensing would fall. And

00:30:10

I talked to folks who

00:30:11

have said compulsory licensing will

00:30:13

never happen if it didn't

00:30:14

happen during a global pandemic.

00:30:16

When would it ever happen?

00:30:17

I guess. I don't quite

00:30:20

subscribe to that view just

00:30:21

because the first attempt at

00:30:22

something didn't come to fruition.

00:30:23



Doesn't mean that the people

00:30:24

who wanted it to happen

00:30:25

or going to give up.

00:30:26

And there's some slight irony

00:30:29

that the, you know, the

00:30:30

World Conference at which compulsory

00:30:32

licensing. And patent waivers was

00:30:34

to have been discussed almost

00:30:36

this time, last year, had

00:30:37

to be canceled, because the

00:30:38

Ultron break out, but the

00:30:41

demand is still there. The

00:30:42

economic situations supporting Arguments for

00:30:45



taking a hard, look at

00:30:49

Pat and waivers and Al's

00:30:50

relicensing remain. And so I

00:30:52

don't think the fact that

00:30:53

it didn't happen during the

00:30:54

pandemic means that it to

00:30:55

get that it won't. Did

00:30:58

I mention is that there's

00:30:59

an increasing focus on manufacturing

00:31:01

we we certainly her domestic

00:31:03

manufacturing from bread, but as

00:31:04

we deal with biologics Gene,

00:31:06

therapies are Lagos. Therapies getting

00:31:09



the manufacturing process, right? Is

00:31:12

very difficult and involves a

00:31:13

lot of Ip. It involves

00:31:15

a lot of Partners. And

00:31:16

if you want to have

00:31:17

a redundant Brazilian process involves

00:31:19

a lot of different jurisdictions.

00:31:21

That means manufacturers are building

00:31:23

up very defined assets in

00:31:25

different parts of the world.

00:31:26

And those are the kind

00:31:28

of assets that that tend

00:31:30

to get involved in investor-state

00:31:33



actions. They may have only

00:31:34

been roughly 20 in the

00:31:36

last 20 years. Not even

00:31:37

that but almost half of

00:31:38

them were state seizures of

00:31:41

distribution or manufacturing assets in

00:31:44

in local countries. And so

00:31:45

with an emphasis on manufacturing

00:31:47

that back in the increase,

00:31:48

I had more but I

00:31:50

think I've gone over time

00:31:51

so I'm going to turn

00:31:51

it over to Marty. I

00:31:53



don't know where is Peter.

00:31:54

Thank you so much that

00:31:54

that was very very comprehensive

00:31:56

than helpful. You know, I

00:31:59

think there's a lot for

00:32:00

us in the, in the

00:32:01

kind of discussion portion to,

00:32:02

to untangle here. But I

00:32:04

think one of the many

00:32:05

headlines that you gave us

00:32:07

was early thinking about IP

00:32:10

protections are important. I think

00:32:14

you also give us a

00:32:15



headline about Clash of legal

00:32:17

cultures and and what these

00:32:19

phrases in in contracts may

00:32:21

or may not mean and

00:32:24

also thinking through kind of

00:32:25

domestic and Offshore Manufacturing complex

00:32:29

all of those things if

00:32:31

you're playing at home are

00:32:33

right for disputes and now

00:32:35

we have no better person

00:32:36

to tell us about how

00:32:37

these disputes manifest and how

00:32:39

we can protect ourselves and

00:32:41



then Marni so take it

00:32:42

away. Marty, thanks Patrick. I

00:32:44

think Peter and Brent did

00:32:46

a really good job setting

00:32:47

the stage for why we,

00:32:49

as lawyers have a lot

00:32:51

of strategic advising to do.

00:32:53

I'm in this area early.

00:32:57

Assuming that there may be

00:32:58

a dispute down the road

00:33:01

as bright mentioned. I mean,

00:33:04

really cross-border can collaboration and

00:33:07

development in life sciences has

00:33:09



really become the norm and

00:33:11

I don't think that's a

00:33:13

trend that's going to reverse.

00:33:15

And so because you have

00:33:17

a lot of cross-border collaboration

00:33:19

and development, Life Sciences companies

00:33:23

are increasingly looking to arbitration

00:33:28

clauses in their agreements, where

00:33:30

they're not going to be

00:33:31

able to reach agreement on

00:33:33

submitting, certain disputes to a

00:33:36

particular court. If you're a

00:33:38

US company and you've entered

00:33:39



into a collaboration agreement with

00:33:41

China, you may very well

00:33:43

agree to an arbitration provision.

00:33:46

Certainly, you likely don't want

00:33:49

to find yourself in the

00:33:50

Chinese courts and there may

00:33:52

be certain reasons why the

00:33:53

Chinese party doesn't want to

00:33:56

litigate here. It goes back

00:33:58

to kind of one of

00:33:58

those fundamental tenets has to

00:34:00

why we have international arbitration.

00:34:02

And I think as we

00:34:03



see an increasing number of

00:34:05

these disputes which everyone's reference,

00:34:07

it's really some of the

00:34:10

same general principles that we

00:34:11

seen across Industries, but this

00:34:14

industry in particular is kind

00:34:15

of globalizing and going cross-border

00:34:18

maybe a bit later than

00:34:20

some others. So, is that,

00:34:22

I thought that as the

00:34:23

lawyer on the funeral, in

00:34:25

addition, to Patrick, who I'm

00:34:28

sure will provide some insights

00:34:29



as well. I could talk

00:34:31

a bit about some of

00:34:32

the legal strategic consideration, given

00:34:35

this great scene setting that

00:34:37

we've had from Brian Peter

00:34:39

and I think I pick

00:34:41

up our Brent left off

00:34:42

on the importance of intellectual

00:34:45

property for Life Sciences. Companies

00:34:48

that really is where your

00:34:50

value is. And so, when

00:34:53

you're drafting your dispute resolution

00:34:55

clause in the very first

00:34:56



Simpson, In your contract companies.

00:34:59

Do you think about their

00:35:02

IP and their IP often,

00:35:04

you know, drives the decision

00:35:06

on how they see any

00:35:08

future disputes are being decided.

00:35:11

So just a couple of

00:35:13

strategic considerations first is the

00:35:16

question of whether I P

00:35:17

disputes or a patent disputes

00:35:20

in particular are going to

00:35:21

be in arbitration or out

00:35:23

and you'd certainly see a

00:35:25



lot of dispute Provisions, which

00:35:27

stay well for this collaboration

00:35:29

agreement will agree to arbitrate

00:35:31

disputes but there's a clear

00:35:33

carve out for IP dispute

00:35:36

or there's a clear carve

00:35:37

out for patent disputes and

00:35:40

I'll mention that. Go back

00:35:43

to come back to that

00:35:44

in a moment but I'm

00:35:47

sure as Brent could also

00:35:48

a test, when you have

00:35:50

one of these IP carve-outs

00:35:52



which is not uncommon, it

00:35:55
can lead to a lot

00:35:56
of legal. Complexity. It is

00:35:58
often hard in these commercialization

00:36:01
agreement or collaboration agreement to

00:36:04
figure out which provisions of

00:36:06
that agreement. If someone alleges

00:36:08
breach, our you're related to

00:36:10
IP or are about you,

00:36:14
no valid IP. So the

00:36:16
words you choose to do

00:36:18
that kind of carve out

00:36:19
or really going to matter.

00:36:20



Whether you're in arbitration or

00:36:22

you're in quarts. And even

00:36:23

if you choose your words

00:36:24

carefully, it can often be

00:36:26

very complex. On the second

00:36:30

is a lot of Life

00:36:31

Sciences. Players are repeat, repeat,

00:36:35

collaborators. You know, they work

00:36:37

together on one strand of

00:36:39

research, but then, they may

00:36:41

see an opportunity to collaborate

00:36:43

on a different, a different

00:36:45

stream of research. And so,

00:36:47



because of that, while some

00:36:49

of these are going to

00:36:49

be better company cases, particularly

00:36:51

for the smaller partner. If

00:36:53

there's a different differential between

00:36:55

the size of the two

00:36:57

parties and other cases, these

00:37:00

parties do see themselves as

00:37:02

wanting to get through this

00:37:04

particular dispute because there may

00:37:05

be collaboration opportunities later. So

00:37:08

very much has the flavor

00:37:09

of a more traditional commercial

00:37:11



arbitration. I'm at least in

00:37:13

some cases where you don't

00:37:15

really want Square sure because

00:37:17

it may be that some

00:37:19

other part of your company

00:37:20

sees another collaboration opportunity with

00:37:23

this particular partner and the

00:37:25

way life sciences, companies tend

00:37:28

to be struck The time

00:37:29

different people responsible for business

00:37:31

development, different people over here

00:37:33

protecting IP different, people over

00:37:35

here drafting the agreement so

00:37:37



they all need to be

00:37:38

talking to each other within

00:37:40

the company and that's an

00:37:41

important strategic role for an

00:37:43

outside lawyer as well. To

00:37:45

make sure that the lawyers

00:37:46

you're working at with aren't

00:37:47

just thinking about their Lane

00:37:49

butter, thinking about the other

00:37:50

way and could get dragged

00:37:52

into any. I'm future dispute.

00:37:54

The frogs ample, you will

00:37:56

often see like to your

00:37:57



dispute. Resolution Clauses, that try

00:37:59

to resolve these disputes through

00:38:01

negotiation before you might get

00:38:04

to an arbitration. I'm for

00:38:06

example, And then that mean

00:38:10

they don't always work but

00:38:11

but but certainly it's something

00:38:13

that a lot of of

00:38:14

collaborators because these collaboration agreements,

00:38:17

you start out, you're feeling

00:38:18

really positive, you got this,

00:38:19

great Synergy, you're hoping it's

00:38:22

going to be a blockbuster

00:38:23



product. So course, you're going

00:38:25

to work everything out. And

00:38:28

then the third point I'd

00:38:31

mention is a strategic consideration.

00:38:33

Is considering whether there's a

00:38:35

way to Avail yourself of

00:38:36

investment, treaty protection. Certainly most

00:38:41

investment treaties, either explicitly or

00:38:44

implicitly. I protect intellectual property

00:38:47

on as a protected investment

00:38:50

and particularly, for a larger

00:38:52

multinational who may have a

00:38:53

fairly complex ownership structure to

00:38:57



begin with, with various parts

00:39:00

of their business distributed in

00:39:02

different regions, throughout the world.

00:39:03

I think it's quite reasonable

00:39:05

particularly if you're entering into

00:39:07

an agreement I woulda party

00:39:09

and a developing country market

00:39:12

or Market that doesn't have

00:39:13

has developed a strong IP

00:39:15

protection that you do consider

00:39:18

investment treaty protection. In terms

00:39:22

of which party is actually

00:39:24

going to sign on the

00:39:26



agreement and to some of

00:39:27

the points that that Brett

00:39:29

made and then Patrick made

00:39:30

as well. We certainly have

00:39:33

seen x n Peters. Well,

00:39:36

we certainly have seen examples

00:39:37

where it's really the government

00:39:40

that steps in and take

00:39:41

some kind of unfair discrimination

00:39:43

Tori, Ash action. Something that

00:39:45

might amount to an expropriation,

00:39:48

we're having that extra layer

00:39:50

of investment treaty protection, is

00:39:52



helpful on the investment treaty

00:39:56

side side of things. So

00:39:59

let me just talk and

00:40:01

it a tad more detail.

00:40:03

So keep it fairly high-level

00:40:05

about these IP dispute. I'm

00:40:07

at least as practitioners at

00:40:10

Covington, my colleagues and I

00:40:12

have found that these IP

00:40:15

carve out I'm off and

00:40:17

don't quite work as intended

00:40:19

and often depends on how

00:40:21

litigious I suppose the parties

00:40:22



are It's not covid. I

00:40:30

test this morning. But often

00:40:39

for example, patent disputes might

00:40:40

be carved out, which means

00:40:42

you're going to arbitrate Trade

00:40:44

Secrets disputes. You're going to

00:40:46

arbitrate other kinds of Ip

00:40:48

disputes. The patent disputes are

00:40:51

going to say to the

00:40:53

US courts. That is often

00:40:55

much harder to implement in

00:40:59

practice and it is, then

00:41:02

it is when written on

00:41:03



paper. So take for example,

00:41:08

a carve-out that's only specific

00:41:11

to patents and not all

00:41:13

IP related dispute. We handled

00:41:16

a case that was a

00:41:17

trade secrets arbitration. This was

00:41:20

the 1.8 billion dollar Trade

00:41:22

Secrets arbitration. I would say

00:41:24

that the value they were

00:41:25

putting their putting on that

00:41:27

arbitration really was diving the

00:41:30

Trade Secrets like as if

00:41:31

they were patented, right? But

00:41:35



in the context, also of

00:41:36

that trade secrets arbitration, there

00:41:38

was a lot of document

00:41:41

disclosure cross-examination, that really went

00:41:46

to a future patent dispute

00:41:47

that hadn't happened yet, which

00:41:50

was going to happen in

00:41:51

the US federal court. While

00:41:54

at the same time, there

00:41:56

was a legitimate Trade Secrets

00:41:59

claim that was also being

00:42:00

arbitrated because the Trade Secrets

00:42:02

or carved out of the

00:42:03



arbitration clause. In that case

00:42:06

against strategically thinking, as a

00:42:08

international arbitration practitioner We had

00:42:12

patent lawyers. I mean addition,

00:42:13

to some folks, you know,

00:42:14

Trade Secrets and I know

00:42:16

enough IP to be dangerous,

00:42:17

but I have had lawyers

00:42:18

on my team cuz every

00:42:19

time anybody said, anything, it

00:42:21

had a huge billion-dollar ramifications

00:42:25

for my clients patents. And

00:42:28

you're not necessarily going to

00:42:29



know that. So knowing like

00:42:31

the type of art of

00:42:32

dispute, you're working within the

00:42:33

international arbitration context. And what

00:42:36

the spillover effects might be,

00:42:37

if you have, you know,

00:42:39

one of these carve-outs is

00:42:40

important. Similarly, the relationship between

00:42:44

if you have a more

00:42:45

General Car about, we had

00:42:46

another case where a carved-out

00:42:49

kind of Ip disputes and

00:42:51

what was being arbitrated, really

00:42:53



where the commercial Clauses of

00:42:56

the contract issues related to

00:42:58

your best efforts xcetera, but

00:43:01

did they have an IP

00:43:02

component? And so we were

00:43:05

arbitrating a dispute, but the

00:43:07

other party ran to court

00:43:09

and said, no, the dark

00:43:11

Tracy should be stayed in.

00:43:12

These matters should be litigated

00:43:13

cuz they really do I

00:43:14

pee. So again your back

00:43:16

talking about the scope of

00:43:17



the arbitration Clause, the precise

00:43:19

language of the carve-out, you

00:43:21

know what, supposed to be

00:43:22

arbitrated and what is not.

00:43:24

I'm so when these corporate

00:43:26

deals are done, I mean

00:43:27

I know this is just

00:43:28

kind of one of those

00:43:29

common adages that no one

00:43:31

pays any attention to the

00:43:32

disputes Claus cuz there's just

00:43:34

excited about their deal at

00:43:36

the eleventh hour, your phone

00:43:38



rings. And someone asks you

00:43:39

to think you look at

00:43:41

the, you know, look at

00:43:42

the disputes Claus before they

00:43:43

sign but particularly where there

00:43:46

that they are these are

00:43:47

about as Peter was mentioning

00:43:50

it can really be. I

00:43:52

can be very you know

00:43:54

very complex. And I think

00:43:56

I'll leave the best efforts

00:43:58

issues to maybe the the

00:44:01

discussion that comes afterwards. But

00:44:04



even these just commercial arbitration

00:44:06

that focus on his best

00:44:08

efforts closet can be very

00:44:11

Looks like, what's the governing

00:44:12

law? What's the understanding of

00:44:14

the best of the best

00:44:16

efforts provision? And some of

00:44:19

those can bleed into my

00:44:20

pee. So there's really a

00:44:22

lot of strategic considerations upfront

00:44:25

and anticipating what type of

00:44:27

dispute you can have and

00:44:28

then once you actually have

00:44:30



that dispute, there's also a

00:44:31

lot of strategic considerations to

00:44:33

consider how the dispute. Your

00:44:35

arbitrating may have ramifications for

00:44:39

for the IP that's held

00:44:43

by your client on more

00:44:44

generally. So, you know, I

00:44:46

pee really I've found at

00:44:48

least is really Court of

00:44:49

these disputes. Even if the

00:44:50

discuss, the arbitration isn't on

00:44:54

its face. Technically about the

00:44:57

intellectual property. So I would

00:45:00



just make a few final

00:45:03

observations one. Is that will

00:45:08

let me say one thing

00:45:08

about best efforts in this

00:45:10

problem which is that you

00:45:11

define the term in your

00:45:13

agreement that can be helpful

00:45:14

a certain way. The UK

00:45:17

and US law is quite

00:45:18

developed on Master. If you

00:45:19

agree to define the terms

00:45:22

best efforts, you might be

00:45:23

in a better spot. So

00:45:25



that's, you know, one way

00:45:26
to deal with it. And

00:45:29
so, finally, in addition to

00:45:30
thinking about these strategic considerations,

00:45:33
both pre-arbitration, and once you're

00:45:35
in the arbitration, I think

00:45:38
thinking about the investment treaty

00:45:41
arbitration is also quite important.

00:45:43
Many of these cases are

00:45:46
just going to be either

00:45:47
or either. It's clearly a

00:45:48
commercial arbitration between private parties

00:45:52
or there's some regulatory issue,

00:45:56



where there's concern that, you

00:45:59

know, it's a I said,

00:46:00

essentially a taking or expropriation

00:46:02

of intellectual property, where there's

00:46:04

maybe been a discrimination or

00:46:07

a potential National treatment violation

00:46:10

or a fair and Equitable

00:46:12

treatment violation through the regulatory

00:46:15

process and all of these

00:46:17

things, I think also need

00:46:19

to be top tip, top

00:46:20

of Mind given as Brent

00:46:23

explain that, this is a

00:46:24



highly regulated environment. And in

00:46:28

a lot of markets, that

00:46:30

highly regulated environment is an

00:46:33

industrial policy tool for countries.

00:46:36

And because it's an industrial

00:46:37

policy tool, you might find

00:46:41

that your life sciences client

00:46:43

my, you know, run into

00:46:46

discriminatory issues, you know, issues

00:46:49

that are arbitrary or you

00:46:54

don't provide the kind of

00:46:56

like regulatory review that that

00:46:59

should be. Acquired or even

00:47:01



could do so much to

00:47:03

pass a regulation or adopt

00:47:05

a law that diminishes. The

00:47:06

value of I pee so

00:47:07

much that it would essentially

00:47:08

affect an expropriation VIP or

00:47:11

a compulsory license. Where is

00:47:15

the compulsory license isn't done

00:47:16

kind of in accordance to

00:47:18

International rules and that provides

00:47:19

for fair compensation. Then you

00:47:22

know, they're also could be

00:47:23

issues. So there's a whole

00:47:24



host of issues in the

00:47:26

regulatory space that can lead

00:47:28

to investment treaty arbitrations, in

00:47:30

addition to a commercial one.

00:47:33

So there's a lot here,

00:47:34

there's a lot going on

00:47:35

and I think I would

00:47:36

say our definite consensus is

00:47:38

these disputes has Patrick mentioned

00:47:40

certainly aren't aren't going away

00:47:42

anytime soon and if anything

00:47:44

we may see more of

00:47:46

them cuz there was a

00:47:47



lot of quick agreements made

00:47:50

during the kind of covid

00:47:52

act. You make the drink

00:47:54

you more later. That was

00:47:55

very, very impressive. Obviously one

00:47:58

of the takeaway is it?

00:47:59

You haven't heard it already

00:48:00

is there's a lot here

00:48:01

right? Another take away. Perhaps

00:48:04

is for those of you

00:48:05

who works as practitioners alongside

00:48:09

patent lawyers go home, say

00:48:12

hey I'm an arbitration practitioner.

00:48:13



We should collaborate more because

00:48:15

there's a lot of work

00:48:16

that we can do for

00:48:17

our clients together. Those that

00:48:20

that obviously is a is

00:48:21

definitely a theme and certainly

00:48:23

one that if you want

00:48:25

to get involved in avoiding

00:48:27

a dispute is is essential.

00:48:29

Let me kick off the

00:48:30

kind of question Fizz with

00:48:32

a question I think for

00:48:33

Brent and and Peter morning,

00:48:36



if you want to jump

00:48:36

in here to what's the

00:48:38

movie? We heard a lot

00:48:39

about the US, right? And

00:48:41

this concept of ensuring the

00:48:45

the kind of pan do,

00:48:47

I don't use the word

00:48:49

threat depend on my policy,

00:48:51

thoughts about compulsory licenses for

00:48:53

things, the public health related

00:48:55

issues, but obviously, Europe is

00:48:58

also quite the sea. Essential

00:49:00

Andrew bus Innovative market and

00:49:03



we haven't heard anything about

00:49:04

what they're doing. It would

00:49:06

be interesting to kind of

00:49:07

get a sense from from

00:49:08

a European perspective or or

00:49:10

any other Innovative Market what

00:49:12

you're seeing there, and then

00:49:14

maybe we'll will broaden it

00:49:15

up a little bit and,

00:49:16

and get back to disputes.

00:49:17

Thank you. And I would

00:49:21

just know we can and

00:49:23

we do make fun. I

00:49:25



make fun at ease, a

00:49:26

little bit of us. FDA

00:49:27

people with all of her

00:49:28

acronyms and you mentioned the

00:49:32

granddaddy of all the user

00:49:34

fee act switch is prescription

00:49:35

drug and since the creation

00:49:38

of a user fee act,

00:49:39

I believe is 1992. You

00:49:41

had other regulated Industries have

00:49:44

user fee X adopted as

00:49:48

well. Generic drug user fee

00:49:49

medical device user fee. I

00:49:52



was similar user fee, Oliver

00:49:54

reauthorization this year and then

00:49:56

there are a couple animal

00:49:56

drug user fees for next

00:49:58

year and the nose. Behind

00:50:00

this, these acts is 30

00:50:04

years ago. You would see

00:50:07

country of first introduction or

00:50:09

area of first introduction of

00:50:11

new therapies be Europe. There

00:50:15

was a case made that

00:50:17

the FDA was taking too

00:50:18

long to adopt new therapies

00:50:21



and it was a better

00:50:22

idea of a half a

00:50:23

manufacturer's. They thought to go

00:50:25

to Europe and seek approval

00:50:27

and then have these products

00:50:28

in the hands of Europeans,

00:50:30

prior than Americans due to

00:50:31

the lack of predictability at

00:50:33

the FDA and what to

00:50:35

use. If you have something

00:50:36

over that time is manufacturers

00:50:39

will pay a fee for

00:50:41

review of their application and

00:50:43



then the products that they

00:50:45

have on the market and,

00:50:46

and facilities, and in exchange

00:50:48

for that, the FDA will

00:50:49

commit to reviewing therapies, overall,

00:50:53

much more quickly and safely,

00:50:56

but just in a more

00:50:57

diligent fashion and in the

00:50:59

Thirty years since enactment of

00:51:01

the prescription drug user fee

00:51:03

act, you've seen the country

00:51:05

first introduction to come the

00:51:06

United States of America rather

00:51:08



than, and your appendix is

00:51:09

no much more Capital coming

00:51:13

to the United States, much

00:51:14

more manufacturing, coming to the

00:51:16

United States because FDA has

00:51:17

become just as Richard in

00:51:19

terms of safety demands as

00:51:21

they always have been, but

00:51:23

they begin flexibilities as well.

00:51:25

And they now or more

00:51:27

appropriately resource, and we've seen

00:51:30

the therapies, come to the

00:51:32

benefit of US citizens more

00:51:34



so quickly than your father's

00:51:36

can look at certain price

00:51:38

controls that they have in

00:51:39

Europe and that is another

00:51:42

reason you seem much more

00:51:42

investment in the United States.

00:51:44

But when I speak to

00:51:46

the companies, I represent, they

00:51:50

have no deep concern with

00:51:53

emea, which is European Body,

00:51:55

their review of But they

00:52:01

all agree that the United

00:52:02

States through the Investments that

00:52:04



they and the US government

00:52:05

have made in the FDA

00:52:06

and a regular took the

00:52:08

regulations by the FDA and

00:52:09

flexibility to the FDA that

00:52:11

it is a more predictable

00:52:15

place and better place to

00:52:17

first, introduce their products. Go

00:52:20

USA. What we seen the

00:52:24

commercial behavior of our of

00:52:25

our manufacturer clients has the

00:52:27

duty of the Paducah date

00:52:28

is a landmark and that

00:52:31



is banked on for development,

00:52:33

commercialization investment reasons. And there

00:52:36

is that predictability what I've

00:52:40

seen more in in looking

00:52:42

at European, at least on

00:52:43

the commercial arbitration side is

00:52:45

in the US, we have

00:52:48

the FDA for approval and

00:52:50

in Europe. The approval is

00:52:52

off and rolled up with

00:52:54

the reimbursement and so it's

00:52:58

often the case that a

00:52:59

global manufacturer who wants to

00:53:02



launch a therapy in multiple

00:53:04

jurisdictions, has to think hard

00:53:05

about how to launch in

00:53:07

Europe, what country to approach

00:53:09

first, if it's going to

00:53:10

go several at once, or

00:53:11

if it's going to Target

00:53:12

the Big 5 or starting

00:53:14

a particular case and it's

00:53:18

it's been chaos Brinkley in

00:53:22

that, there's many many examples

00:53:24

where, what was thought to

00:53:25

be a kind of Friendly

00:53:28



environment to be a first

00:53:30

Outreach for Europe, didn't end

00:53:32

up being so and it

00:53:33

gets tied up and remember

00:53:34

it up. I don't care

00:53:35

if he gets tied up

00:53:36

and reimbursement decisions and suddenly

00:53:37

the European watch as a

00:53:38

whole is lagging. And again,

00:53:40

it did brings in all

00:53:42

those questions about should that

00:53:43

have been foreseeable or not?

00:53:45

Just because we, we, we

00:53:46



don't have the same kind

00:53:48

of predictability. That's a that

00:53:50

the house has worked. So

00:53:52

diligently on well as to

00:53:54

spoil your sweet we thrive

00:53:55

on chaos so that's that's

00:53:58

good. I might add one

00:53:59

observation that you Market. I

00:54:01

mean a lot of international

00:54:02

arbitration than life sciences. Space

00:54:04

are like you asked Europe.

00:54:06

There's plenty of small players

00:54:09

in the, in the US

00:54:10



to collaborate with us some

00:54:12

of the European Giants in

00:54:14

the space and similarly, a

00:54:15

lot of smaller biotech firms

00:54:19

in the EU that a

00:54:22

collaborate with some of the

00:54:23

big us companies. So there

00:54:27

are a lot of come

00:54:28

Show the speeds across the

00:54:29

Atlantic in terms of predictability.

00:54:33

One thing I would say

00:54:34

is that mention of compulsory

00:54:37

licensing. There have been throughout

00:54:40



covid discussions in the World

00:54:42

Trade Organization, as to whether

00:54:45

or not there should be

00:54:47

kind of a broad waiver

00:54:48

to issue, compulsory licenses for

00:54:52

patents for covid vaccines and

00:54:56

then an additional debate related

00:54:57

to Therapeutics and diagnostics for

00:55:00

covid-19 kind of what you

00:55:03

might refer to as the

00:55:04

international regulatory space on the

00:55:06

EU has actually really been

00:55:08

kind of at the Forefront

00:55:09



front of trying to take

00:55:13

that slowly. Making sure that

00:55:15

there's actually a case for

00:55:16

compulsory licensing and essentially being

00:55:19

like the defender of you

00:55:21

know I pee in this

00:55:22

very innovative, you know, cutting-edge

00:55:25

area noting that there's other

00:55:26

ways to make sure. That

00:55:28

vaccines excetra can get distributed

00:55:31

that those who need them

00:55:32

or without a rotating IP

00:55:34

rights, and it's really been

00:55:36



that you are not so

00:55:37

much that you asked that's

00:55:38

been out in front their

00:55:40

place, great point because that

00:55:45

has been the case I

00:55:46

can say, and I spent

00:55:48

time on a hill and

00:55:49

when you're on the hell,

00:55:49

you think, you know, everything

00:55:50

and turns out, you don't

00:55:51

know anything. And then I

00:55:52

went to regulated industry at

00:55:55

by where I was to

00:55:56



have lobbyists at by when

00:55:57

I did get to meet

00:55:58

with a number of CEOs

00:56:00

and other leaders in the

00:56:01

biotechnology field and just to

00:56:03

underscore the points that are

00:56:04

being made, nothing. I mean,

00:56:07

the lifeblood of our technology

00:56:10

and Life Sciences industry is

00:56:12

intellectual property. It's by far,

00:56:14

the most important thing, it

00:56:15

allows you with strong Pattinson

00:56:17

certain pets to go out

00:56:19



there a tenth as well.

00:56:20

FDA granted the exclusivity. That's

00:56:22

a whole different things but

00:56:23

you know, that's another protection

00:56:25

that from FDA to not

00:56:27

agree. Edit the product, it

00:56:29

generic come product for certain.

00:56:32

Of time, but that's what

00:56:34

allows Life Sciences. Companies of

00:56:38

all sizes, go out and

00:56:39

get the capital that they

00:56:40

need to go down the

00:56:41

path of trying to commercialize

00:56:45



the product of the course

00:56:46
of 10 15, 20 years

00:56:47
and these threats to Life

00:56:50
Sciences. Were they be the

00:56:51
international ones, Martis, mentions or,

00:56:53
you know, Mark and rights

00:56:55
under bidole act in the

00:56:57
United States, that abuse or

00:57:00
threats, which unfortunately come up

00:57:04
every now and then, which

00:57:05
really are of the greatest

00:57:07
concerns because the only way

00:57:09
that folks are going in

00:57:10



the best of billions of

00:57:11

dollars necessary to develop new

00:57:12

Therapeutics is with the assurance

00:57:13

that they can protect these

00:57:16

from competition for a. Of

00:57:18

time. And if you then

00:57:19

have whether the domestic US

00:57:21

government or international government saying

00:57:23

that during because his ex-wife

00:57:28

That really is chilling to

00:57:30

investment in life sciences. Well,

00:57:33

I like the the continued

00:57:35

use of Life blood since

00:57:37



we are talking about life

00:57:38

sciences. I mean, we did

00:57:39

hear a lot about the

00:57:40

kind of concerned about exclusivity.

00:57:43

We haven't even invoked Waxman

00:57:46

but we'll come back to

00:57:47

that. Perhaps two things just

00:57:49

to throw it on the

00:57:50

table. So that folks can

00:57:51

pick it up and talk

00:57:52

about it is we haven't

00:57:53

really spoken about generics in

00:57:55

this in this space and

00:57:58



the other thing we haven't

00:57:58

really chatted about is and

00:58:01

I know Marty can probably

00:58:02

speak to this too. Is

00:58:04

that the exclusivity periods? Or

00:58:06

that kind of Ip protections

00:58:07

and some of the multi-national

00:58:09

big regulatory big treaties, right?

00:58:12

So there was a lot

00:58:13

of criticism back when the

00:58:14

United States was a signatory

00:58:17

of the TPP about the,

00:58:19

the, the protection, that the

00:58:21



United States helped broker in

00:58:23

the IP space, and as

00:58:25

one of the leading Innovative

00:58:26

markets in the world, Probably

00:58:29

a lot of your clients.

00:58:29

Brent, we're not thrilled with

00:58:31

with what the United States

00:58:33

provided for, in that agreement.

00:58:34

So we can, we can

00:58:35

talk a little bit about

00:58:36

that to let me just

00:58:38

shift gears for a second

00:58:39

and talk about Trade Secrets

00:58:43



and, and go back to

00:58:44

basics. You are a lawyer

00:58:47

to go back to basics.

00:58:50

And those Basics are arbitration

00:58:53

requires Trivedi, right? And When

00:58:57

someone steals or is attempting

00:58:59

to steal your IP and

00:59:02

there's a trade secret issue,

00:59:03

you don't always have direct

00:59:06

privity with those with that

00:59:07

person. Like, I'm thinking about

00:59:09

a rogue employee or something

00:59:10

else. So how do we

00:59:12



get around those tricky? Little

00:59:14

issues in in the trade

00:59:16

secrets space. Anyone want to

00:59:17

handle that? These were not

00:59:22

pre-planned questions, if that's, if

00:59:24

that's too much of a

00:59:25

stump stumper, or it's improperly

00:59:28

phrased to let me know.

00:59:32

Brent, go first. There it

00:59:33

is. Haha. Okay, well that

00:59:37

bought enough time for the

00:59:39

most competent person on the

00:59:40

panel to answer it. In

00:59:43



my experience that hasn't actually

00:59:45

really been an issue in

00:59:49

that it's been kind of

00:59:51

a company to company. You

00:59:54

know, you stole our Trade

00:59:55

Secrets allegation. And even if

00:59:59

it's pinned on a date

01:00:01

of which specific, you know,

01:00:03

actors might have done. The,

01:00:05

the stealing really that the

01:00:08

companies are responsible for the

01:00:10

actions of their place. So

01:00:11

it hasn't actually, you know,

01:00:14



manifest itself. Now, what I

01:00:15

could see because of the

01:00:17

interaction between these International arbitration

01:00:19

and litigation is you could

01:00:22

see a situation where you

01:00:24

know company is just Company

01:00:26

B, you know, for because

01:00:29

they're Rogue employee, you know,

01:00:31

torque but the trade secrets

01:00:33

of company a and then

01:00:34

left. Start company C or

01:00:36

something like that. And Company

01:00:37

B is like a better

01:00:38



Target. You know, you could

01:00:40

see some then, parallel litigation

01:00:42

where Company B sues its

01:00:44

former employee. So I could

01:00:47

spin off into In two

01:00:50

other kind of parallel litigation

01:00:54

tracks. And I have seen,

01:00:55

you know, situations where again

01:00:58

going to the messiness of

01:01:00

these carve-outs where, you know,

01:01:03

if your have a trade

01:01:05

secrets litigation. But it it's

01:01:06

really kind of a patent

01:01:07



dispute disguised as a trade

01:01:09

secrets litigation, then, maybe one

01:01:12

of you could go to

01:01:13

court and get like a

01:01:14

declaratory judgment that you didn't

01:01:16

infringe the patent or something

01:01:17

like that, I would run

01:01:18

in parallel. So I think

01:01:20

you could have parallel litigation

01:01:21

against the Rogue employee. If

01:01:23

that's truly the case, I

01:01:25

think they then be knowledge.

01:01:27

You have to consult your

01:01:28



patent College. We have to

01:01:29

consult your employment law colleagues

01:01:31

still. Like, when you're responsible

01:01:33

for the Rogue employee, or

01:01:34

whether you're some kind of

01:01:35

Defense, I'm so I think

01:01:37

it could, it could play

01:01:38

in but I think it

01:01:40

would be litigated and contested

01:01:42

issue because in my experience

01:01:43

is the companies responsible for

01:01:47

the trade-secret theft in terms

01:01:48

of the allegations So but

01:01:51



it also, I guess the

01:01:52

last thing I would say

01:01:53

is if it is truly

01:01:54

that you know it may

01:01:57

be a dispute. That's resolved

01:01:59

short of completing the arbitration,

01:02:02

the parties, the best. You

01:02:05

anticipated, the exact fact that

01:02:07

I've litigated. I mean we

01:02:09

had a situation under a

01:02:10

licensing agreement that we allege

01:02:12

there was a patent infringement

01:02:14

that infringement case went forward

01:02:17



in the in the kind

01:02:18
of us courts. But in

01:02:20
parallel there was the possibility

01:02:22
because of the draft arbitration

01:02:24
clause in the licensing agreement

01:02:25
to bring a parallel arbitration

01:02:26
on different issues and it

01:02:29
was actually the threat of

01:02:30
the arbitration that resolves the

01:02:32
overall dispute because the Patton

01:02:36
courts were taking a while

01:02:38
and it's too high risk

01:02:40
for both parties to have

01:02:42



a disposition on on the

01:02:44

patent. At and the real

01:02:46

issue was the potential improper

01:02:49

use of of the, the

01:02:50

product under the licensing agreement,

01:02:51

which was resolved through the

01:02:54

threat of arbitration in an

01:02:55

imminent damage which was going

01:02:57

to go a lot quicker.

01:02:57

So arbitration is a tool

01:03:00

in the kind of, let's

01:03:04

say, more kind of prosaic

01:03:06

litigation strategy, that a lot

01:03:08



of our clients are going

01:03:10

to be interested in another.

01:03:12

Another question I had in

01:03:14

this one is I guess

01:03:16

for Peter and Marnie is

01:03:20

she mentioned ists or investment

01:03:23

treaty protections. What are the

01:03:25

compulsory licenses is certainly one

01:03:27

of them but what are

01:03:28

the other kinds of State

01:03:29

actions that could give rise

01:03:30

to a dispute in this

01:03:33

space? Just kind of throw

01:03:35



some of those out on

01:03:36

the table. Yeah, well in

01:03:39

the NAFTA, dispute between Lily

01:03:42

and Canada, it had to

01:03:44

do with the failure to

01:03:45

provide patent protection, in accordance

01:03:49

with International standards in the

01:03:51

standards that are in the

01:03:52

the treaty. It also can

01:03:54

be on the new regulatory

01:03:56

side where the country's regulatory

01:04:02

approval to generics for products

01:04:06

that are still protected by

01:04:07



patents and the interplay between

01:04:10

the IP protections and the

01:04:12

Regulatory and data exclusivity protections

01:04:17

there. And you know I

01:04:20

can as I said for

01:04:23

me and my experience some

01:04:26

of the investment treaty issues

01:04:28

really are when I pee

01:04:30

kind of bleeds over into

01:04:32

industrial policy. So you know,

01:04:34

if there is a domestic

01:04:36

Champion that a company Are

01:04:39

there a country or their

01:04:41



regulatory authorities are trying to

01:04:42

help particularly say? I know

01:04:45

a generic company that would

01:04:47

like to have access to

01:04:48

some of the IP information

01:04:50

that the government has a

01:04:53

because of the regulatory approval

01:04:54

process. Then there could be

01:04:57

some misuse of that intellectual

01:05:00

property that also could run

01:05:02

afoul of investment treaty protection.

01:05:06

So those are just some

01:05:07

of the issues that come

01:05:10



to mind, but you also

01:05:11

I know have arbitrator in

01:05:13

this area. So my father's

01:05:14

other thought, well, I just

01:05:15

just kind of 12 finger

01:05:17

follow up on that. Do

01:05:18

you see? Did you see

01:05:21

governments laying claim to too?

01:05:25

Kind of some of the

01:05:26

defenses that they might have

01:05:28

with regard to public policy

01:05:29

essential security card balance during

01:05:31

pandemic things like that playing

01:05:33



more ascendant role in in

01:05:35

investment disputes or do you

01:05:38

mean industrial industrial policy tool?

01:05:41

Sounds like a claimant's Prayers.

01:05:45

If you were representing the

01:05:46

government, you could say, well

01:05:48

this is a matter of

01:05:48

public policy and public health,

01:05:50

and therefore it's not covered

01:05:51

under the treaty. So I

01:05:53

think the public policy exception,

01:05:55

I mean that would be

01:05:56

my go to its public

01:05:58



health of its public policy

01:06:00

and that is a go-to

01:06:01

for many governments and I

01:06:02

think you know, it's going

01:06:03

to be it's an arbitrator's

01:06:05

job to try to sort

01:06:07

through, you know, what is

01:06:08

a legitimate public policy exception

01:06:11

and what is not. So

01:06:14

I think yes, like that's

01:06:15

an issue that we'll get

01:06:16

litigated in almost any life

01:06:19

sciences related, investment treaty to

01:06:22



spew in my view because

01:06:23

it's, that's available to say,

01:06:25

like, what we needed to

01:06:26

do this because it's in

01:06:27

the public interest. But I

01:06:28

think that that is really

01:06:30

the, the beginning of a

01:06:32

conversation and scrutiny by the

01:06:34

arbitrators, and not really an

01:06:37

endpoint, because there may have

01:06:39

been other ways to go

01:06:40

about it, you know, was

01:06:41

it done in a manner

01:06:42



consistent with Weather IP obligations

01:06:46

and international IP Norm. So

01:06:48

I think it it's kind

01:06:50

of it's a starting place

01:06:51

but not really the ending

01:06:52

bending place. That would be,

01:06:53

that would be my view

01:06:55

and National Security. We can

01:06:58

all probably have an opinion

01:06:59

on that, but in my

01:07:01

mind it's not a good

01:07:02

fit for this situation. I

01:07:05

guess I would just like

01:07:06



Omar knees, and same to

01:07:07

you. We have that. We

01:07:08

had a case where involving,

01:07:09

a taking of a distribution

01:07:10

Network and absolutely. The first

01:07:13

offense was public health, it's

01:07:15

in the, it's in the

01:07:15

public good. That may be

01:07:18

an easier argument to make,

01:07:19

when you're talking about a,

01:07:20

you know, media James here

01:07:22

is gene therapy center or

01:07:23

the side of us that

01:07:25



we have a clinical trial

01:07:26

and it was, it was

01:07:29

a bit more difficult than,

01:07:31

in that case that the

01:07:32

arbitrator's where we're fairly concerned

01:07:35

about the legitimacy of a

01:07:37

public policy, I mean, is

01:07:41

it public policy to try

01:07:43

to on Shore or Force

01:07:44

Supply? Chains back back on

01:07:46

tour in a there could

01:07:48

be damaged there to to

01:07:49

those folks who can do

01:07:50



it with better margins offshore

01:07:52

and now we're being forced

01:07:54

it to move forward. So

01:07:57

let me, let me see.

01:07:57

We have about 10-15 more

01:07:59

minutes, folks in the audience

01:08:01

had any questions. Don't be

01:08:05

bashful. Yes, please. If you

01:08:06

could just, we could get

01:08:08

you a microphone. We have

01:08:11

to use this one. Sorry.

01:08:16

Thank you for this bike.

01:08:19

So thank you. Thank you

01:08:20



for this morning has been

01:08:26

wonderfully or an introduction to

01:08:29

that topic. Forgive my ignorance,

01:08:30

why? What is the purpose

01:08:33

of carving out patent disputes

01:08:35

in the dispute. Resolution close.

01:08:39

Peter gave me the mic.

01:09:36

Background background. Mike's on, but

01:09:43

they can hear us at

01:09:44

home too, so that's good.

01:09:45

Okay. And I can protect

01:09:47

so, so so in my

01:09:50

mind, you know, that is

01:09:51



one of the issues, its

01:09:53

predictability, I'm its expertise. It's

01:09:56

the fact that you have

01:09:58

relied on your, for, your

01:10:00

US Patent. You know, you've

01:10:01

relied on a certain set

01:10:03

of us standards and it

01:10:06

kind of happened to your

01:10:07

product at its. Unless you,

01:10:09

you've decided you're going to

01:10:11

have like three pain experts,

01:10:15

as your arbitration panel who

01:10:18

will be applying US law.

01:10:19



There's some risk. There's also

01:10:20

no chance of appeal and

01:10:22

to use our favorite phrase,

01:10:23

the lifeblood of these companies

01:10:26

is IP. A lot of

01:10:28

General, counsel's are quite wary

01:10:32

of there. Being no appeal

01:10:34

process with regards to litigating

01:10:37

a patent. So that that's

01:10:38

in my experience. I'm sure.

01:10:42

Observations very consistent, even in

01:10:44

the US. If you just

01:10:46

look at litigation, there's a

01:10:47



remarkable amount of that at

01:10:49

the circuit court level of

01:10:52

overruled Ip decisions. And it's

01:10:55

often the case that when

01:10:56

were involved in a dispute

01:10:57

from the start, the parties

01:11:00

know that they're really positioning

01:11:01

themselves for a later trial

01:11:02

because in the first instance,

01:11:04

they have a judge who

01:11:05

isn't burst in the architecture

01:11:06

of Ip law and all

01:11:08

the intricacies of the IP

01:11:09



issues. And so they're really

01:11:11

establishing a record and I

01:11:12

think you see the same

01:11:13

thing in arbitration. It's really

01:11:15

difficult you know speak about

01:11:19

finding arbitrators to both have

01:11:22

the subject matter knowledge to

01:11:24

arbitrate these disputes are free

01:11:26

of any kind of encumbrances

01:11:28

that would make it inappropriate

01:11:29

for them to hear them.

01:11:31

And then you want them

01:11:32

to be IP experts on

01:11:33



top. That's that's a very,

01:11:35

very tall order and you

01:11:36

might be able to find

01:11:37

three people and they might

01:11:38

be able to schedule you

01:11:39

in a two and a

01:11:40

half years from now. You

01:11:42

get the tents to really

01:11:44

be a potential drag on

01:11:47

on the arbitration process. Not

01:11:48

that I think it's a

01:11:49

walk in the park trying

01:11:50

to run a parallel arbitration

01:11:52



with an with an IP

01:11:53

carve out some time in

01:11:55

for investment treaty arbitration. And

01:11:57

also want, probably those arbitrators

01:11:59

to have some familiarity with

01:12:00

public international law and how

01:12:01

to read a treaty. So

01:12:02

later that on top two

01:12:03

of you were looking to

01:12:05

be a unicorn in the

01:12:06

space. Now, you know what,

01:12:08

you need to get expert

01:12:09

on and then you'll get

01:12:09



appointment. Other other questions from

01:12:12

the audience. Set the mic

01:12:17

on the table. You might

01:12:18

not hear it in the

01:12:18

room but it is coming

01:12:19

through at home. So if

01:12:20

you can hear us, then

01:12:21

we can use the mic

01:12:22

on the table. Thank you

01:12:25

very much for all the

01:12:26

enlightenment that you have provided.

01:12:28

I had a thought concerning

01:12:32

what is becoming or has

01:12:35



become a trend with respect

01:12:37

to to trade at which

01:12:39

is trying everyone, perhaps let

01:12:42

buy it by the us

01:12:43

at some stage, but everyone

01:12:44

is really trying to bring

01:12:46

production on Shore and and

01:12:49

somehow require National produce or

01:12:54

or input sensor. And that

01:12:56

made me think about the

01:12:58

performance requirements that are in

01:13:00

various free trade agreements. Mostly

01:13:03

had those that by the

01:13:05



us but in general in

01:13:06

free trade agreements. We don't

01:13:07

we don't have performance requirements

01:13:10

in necessarily in the old

01:13:14

model bilateral. Entreaties. And, and,

01:13:16

and that made me think

01:13:17

whether or not for Life

01:13:20

Sciences, because be sure of

01:13:22

whether you going to produce

01:13:23

on Shore or elsewhere. In

01:13:26

the our time that Tetra

01:13:27

comes to mind whether the

01:13:30

network of investment treaties including

01:13:33



fdsfds generally do but but

01:13:36

those are not most of

01:13:37

the bilateral investment treaties, whether

01:13:40

the network network of investment

01:13:42

treaties is Israeli. ready or

01:13:47

or provides the tools to

01:13:51

prevent. Did the performance requirements

01:13:55

that? Why would she be

01:13:57

in in another, in in

01:14:00

free trade agreements and whether

01:14:01

that is a rather than

01:14:03

issue for Life Sciences. So

01:14:07

any any takers on that?

01:14:08



I do think that the

01:14:11

majority of markets where you

01:14:16

have let you know this

01:14:19

question posed, whether it be

01:14:20

as an Innovative Market or

01:14:22

Market are in some ways

01:14:24

at this point. Covered under

01:14:26

one of the larger ftas,

01:14:28

as the spaghetti Bowl goes

01:14:29

and the end of the

01:14:30

clever use of for greater

01:14:33

certainty retroactively, perhaps cover some

01:14:37

of the first and second-generation

01:14:38



bits. I'm not sure if

01:14:39

that's directly responsive. It's, it's,

01:14:42

it's an absolutely good point.

01:14:43

I, I, I, I am

01:14:46

not aware of the 20

01:14:48

cases, that, Peter mentioned that,

01:14:50

that, that question is, is

01:14:53

But I do think that

01:14:55

one of the interesting things

01:14:56

will be how robust some

01:14:57

of those FDA is that

01:14:58

that include some of these

01:15:01

Innovative Concepts retroactively work backwards

01:15:05



to handle, some of the

01:15:06
less robust B. But I

01:15:09
mean this this goes to

01:15:10
a larger discussion about whether

01:15:12
1st and 2nd generation, bilateral

01:15:14
investment, treaties are going to

01:15:15
survive over the next 10

01:15:16
years. Might my own suggestion

01:15:17
is that it will be

01:15:19
very difficult for them to

01:15:20
persist, but that's just my

01:15:21
view Barney. take, take take

01:15:25
this one with some Okay,

01:15:30



we've got the better microphone

01:15:31
now, I agree. It's a

01:15:34
very good question. I mean,

01:15:35
I think gone older B.

01:15:36
It really might depend on

01:15:38
how it's implemented because you

01:15:39
could see it be implemented

01:15:41
in a way that could

01:15:42
give rise to some kind

01:15:45
of national treatment around my

01:15:46
phone claim or maybe it's

01:15:48
implemented. Like, in a very

01:15:50
kind of arbitrary way. So

01:15:51



in my mind and maybe

01:15:53

also for older generation B,

01:15:56

I think there's a question.

01:15:57

Is there a Gap? Or

01:15:58

maybe depending on how it's

01:16:02

implemented? You could still do

01:16:04

something, but I do think

01:16:05

that To your point. I

01:16:08

mean right now this idea

01:16:09

like onshoring as part of

01:16:11

an industrial policy after it

01:16:13

is something that everyone's doing

01:16:15

and I don't think I

01:16:16



got another face of it.

01:16:17

That itself would be a

01:16:18

treaty violation. But I do

01:16:20

think to your point like,

01:16:22

well how you do it,

01:16:23

you need to be thinking

01:16:24

about these International obligations, and

01:16:28

I'm sure Brent can a

01:16:30

test from a Time on

01:16:31

the hill, whenever our Congress

01:16:33

is, considering are these types

01:16:35

of Provisions are. There's usually

01:16:37

plenty of people up there

01:16:38



kind of whispering in the

01:16:39

ears of folk saying, you

01:16:41

know, hey, the US has

01:16:42

a lot of international agreements

01:16:43

topic that you probably should

01:16:45

consider as your drafting or

01:16:47

legislation. So, I imagine there's

01:16:49

a way to do it.

01:16:50

That's consistent with those obligations,

01:16:52

but there's probably also wasted

01:16:54

you at that would be

01:16:55

inconsistent. And bring can tell

01:16:56

us how, how well-received there

01:16:58



that the statement to Congress,

01:17:01
there are a lot of

01:17:02
International Airport received that phrases.

01:17:06
Oh yeah, there was like

01:17:07
oh okay well then we

01:17:08
won't touch it as well.

01:17:12
Any other questions from the

01:17:14
audience? Does a question online?

01:17:17
Excellent. Jose Antonio, would you

01:17:21
like to to to be

01:17:22
our online? The face of

01:17:25
the online community. Show the

01:17:37
questions from Laura Richardson, and

01:17:40



it's to Peter. So, there

01:17:42

you go. Given the difficulties

01:17:44

and inherent speculation required in

01:17:47

quantifying Damages in life sciences.

01:17:49

Dispute, has there been any

01:17:51

consideration or attempt to include

01:17:54

liquidated? Damages Clauses in life

01:17:57

sciences, commercial collaboration agreements for

01:18:00

breaches of certain terms and

01:18:02

parentheses such as are common

01:18:05

in construction agreement, or there's

01:18:08

a second question or are

01:18:11

their unique features in the

01:18:12



Life Sciences field, that wouldn't

01:18:15

would not lend itself to

01:18:17

liquidated damages causes That's an

01:18:21

excellent question. Well well, he's

01:18:22

getting a microphone. I'm sure

01:18:23

French are well-versed in liquidated.

01:18:26

Damages Clause is speaking of

01:18:27

kind of cross, cultural conflict,

01:18:29

between innovators in other jurisdictions.

01:18:31

Now that you have found

01:18:32

that was why I can't

01:18:35

speak to the universe but

01:18:36

only infrequently come across attempts

01:18:39



to introduce the concept of

01:18:41

liquidated damages within a life

01:18:42

sciences contact. I think the

01:18:45

challenges are typically that if

01:18:48

you takes a trade secret

01:18:50

misappropriation, where are you? You

01:18:53

for some of your .45

01:18:54

protocols or are they may

01:18:57

be at being expropriated, they're

01:19:00

still value and the company

01:19:02

doesn't want liquid ant baits.

01:19:03

What they want is to

01:19:04

continue the development of their

01:19:05



products and usually 2 to

01:19:09

block the party. This Miss

01:19:12

appropriate the assets in. So

01:19:14

it's often the case that

01:19:15

we find ourselves in a

01:19:17

little bit of a difficult

01:19:18

situation where we are To

01:19:20

assess damages with the hope

01:19:22

that it's irrelevant because the

01:19:23

real goal of their arbitration

01:19:26

is to secure the IP

01:19:27

to secure the path forward

01:19:28

and to ensure that the

01:19:32



kind of ancillary roads to

01:19:34

investment remain open. And I

01:19:36

think, maybe maybe that's the

01:19:37

key. Is that, you know,

01:19:39

those in life sciences, know

01:19:40

that the product that comes

01:19:42

to Market sometimes Bears, a

01:19:44

resemblance to what you thought

01:19:45

you'd bring 20 years ago.

01:19:47

But often the case, it's

01:19:49

that along the path. You

01:19:52

found other opportunities, other therapeutic

01:19:55

categories, other aspects of the

01:19:58



product to be developed so

01:19:59

that you have a therapy

01:20:00

that still valuable to patients,

01:20:02

still commercially viable, but not

01:20:04

exactly where you thought you'd

01:20:06

end up. And, and the

01:20:07

question of whether the promised

01:20:09

utility is, is needs to

01:20:12

be specified, has been litigated

01:20:14

in in our space right

01:20:15

now. I would just add

01:20:17

that to Peter's point. I

01:20:18

have clients who start Down

01:20:21



who acquired assets which are

01:20:25

decades-old protections for the indication

01:20:30

and the like, but like

01:20:31

I could think of on

01:20:32

which was a weight loss

01:20:33

drug, which ultimately was brought

01:20:34

to the market for Pediatric

01:20:36

epilepsy. You just never know

01:20:38

where the science is going

01:20:40

to lead you with products.

01:20:44

We have time for one

01:20:45

more question, don't be, don't

01:20:47

be shy. Anything else online?

01:20:52



One more question. It's David

01:21:00

Engel from a delivery. Thank

01:21:01

you for the panel, just

01:21:02

a question on potential threats

01:21:03

to to Life Sciences. It

01:21:07

seems to make more this

01:21:08

requires billions of dollars to

01:21:10

invest it in the night

01:21:11

and I did it extremely

01:21:13

likely to fail. I'm I'm

01:21:15

actually it's much easier to

01:21:16

to get financing to commit

01:21:18

financing. This idea when your

01:21:19



monetary environment, where is 11

01:21:22

Crest Drive? Liquidity. Sloshing around

01:21:25

in also with your interest

01:21:27

rate environment, flat is the

01:21:28

present value of potential profits

01:21:31

in twenty years time as

01:21:33

we have to move out

01:21:34

of that era. When money

01:21:35

is little more expensive and

01:21:37

we didn't get those advantages,

01:21:38

is that a huge threat.

01:21:40

I'll be going to see

01:21:41

a reduction in innovation in

01:21:43



the future. I don't say

01:21:44

so, Is that a possibility

01:21:47

that they'll be far more

01:21:48

disputes? And typically we think

01:21:49

when it's less money sloshing

01:21:50

around, people, get paid for

01:21:52

their respects to get paid,

01:21:53

something you get dispute. So

01:21:55

is that a threat? Would

01:21:56

I have to cut everybody

01:21:57

off but I'm asking about

01:21:59

20, no. We start with

01:22:01

some litigations and let me

01:22:07



just start with, thank you.

01:22:08

It's not, it's not going

01:22:12

to be good for the

01:22:13

US government for the research

01:22:17

and development into new therapies

01:22:19

vaccines and the like by

01:22:22

implementing on the number to

01:22:25

Rexburg e r. A first

01:22:28

a price setting of a

01:22:30

of a maximum fair price

01:22:33

for a product. And then

01:22:34

a negotiation downward on that

01:22:37

price which is going to

01:22:38



be which is what is

01:22:40

mandated by the inflation reduction

01:22:43

act that the pharmaceutical industry

01:22:44

to biotechnology industry were very

01:22:47

concerned very opposed to the

01:22:51

notion that the government can

01:22:52

be directly negotiating on a

01:22:53

subset of very important Therapeutics

01:22:55

and they contend and I

01:22:56

agree with them that this

01:22:58

is going to be too,

01:22:58

unfortunately, less. Development. I've already

01:23:02

seen one company indicate that

01:23:03



they're not pursuing an indication

01:23:05

which they, otherwise would because

01:23:07

they did not want to

01:23:08

potentially in the number of

01:23:11

years, be subject to direct

01:23:13

negotiation with new play. Some

01:23:14

reduction act calls for so

01:23:16

that is of of great

01:23:18

concern to a life sciences

01:23:20

community. I absolutely agree with

01:23:24

French, in the, in, in

01:23:25

the short-term, Mark conditions, change

01:23:28

economic conditions, change investment in

01:23:30



life, sciences remains relatively stable,

01:23:31

in light of your economic

01:23:35

factors. What what really kills

01:23:36

investment is significant outside action,

01:23:39

anything that that chills the

01:23:41

investment opportunity or or you

01:23:43

know people who invest in

01:23:45

life sciences know they're playing

01:23:46

a long game. What they're

01:23:48

concerned about is the time

01:23:49

consistency problem of some significant

01:23:51

change while they're kind of

01:23:53

waiting for the fruits of

01:23:54



that investment. All that said

01:23:57

it is certainly true. Your

01:23:58

second question it is always

01:23:59

the case that we see

01:24:00

an uptick in disputes when

01:24:03

economic conditions get tight you

01:24:06

know back in 2018 and

01:24:07

it's hard to remember that.

01:24:10

There was a downturn economically

01:24:11

before the pandemic, which kind

01:24:13

of stole the headlines but

01:24:14

they said that was the

01:24:15

most recent example, we saw

01:24:17



where the economy tightened up

01:24:18

and suddenly partners with whom

01:24:20

you were, you were quite

01:24:21

High. The forge ahead with

01:24:23

now you're looking at a

01:24:25

stance and and we see

01:24:29

an uptick in arbitration, we

01:24:31

see an uptick in patent

01:24:32

disputes and we see a

01:24:33

large. I'll take you in

01:24:35

competition claim where everybody's looking

01:24:38

for, you know, some other

01:24:42

Revenue stream or a way

01:24:44



to reduce kind of an

01:24:45
ongoing cost line. Well, we

01:24:54
are at time at, so

01:24:56
let me Falls to me

01:24:58
to say, firstly, my lifeblood

01:24:59
is coffee and lunch and

01:25:01
that will be served outside

01:25:02
to directly after this panel.

01:25:04
But secondly, to thank this

01:25:07
incredible panel, providing very in-depth

01:25:10
insights into life sciences and

01:25:12
how they make late to

01:25:13
the arbitration and thank you

01:25:14



to you our audience at

01:25:16

home and here for your

01:25:18

patience. And of course again

01:25:19

to Jose Antonio, for inviting

01:25:21

us. Also, thank you very

01:25:22

much.