



## The 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 international arbitration and the life sciences sector, highlighting the increasing relevance of this area in arbitration practices. Moderated by Patrick Pierce from Allen & Overy, the panel featured experts including Brent M. Antie from BGR Group, Dr. Peter Rankin from Charles River Associates, and Marni L. Chikata from Covington.

Key themes discussed included the importance of intellectual property (IP) in life sciences, particularly as it relates to collaboration agreements and the complexities of arbitration clauses. The panel noted that a significant portion of international arbitration cases—around 25%—involves IP issues, emphasizing the need for clear definitions and understanding of terms like "best efforts" in contracts, which can vary significantly across jurisdictions.

Brent Antie discussed the regulatory landscape in the U.S. and the push for domestic manufacturing, particularly in the wake of the pandemic, which has prompted lawmakers to examine supply chains and ensure resilience. He highlighted initiatives aimed at bolstering U.S. production capabilities for pharmaceuticals and medical devices.

Dr. Peter Rankin addressed the challenges associated with valuing early-stage IP and the difficulties in quantifying damages in disputes, particularly when collaboration partners may misuse trade secrets. He emphasized the need for effective measures to protect IP throughout the development process.

Marni Chikata discussed the strategic considerations for life sciences companies in drafting dispute resolution clauses, particularly regarding IP disputes. She noted that many companies are repeat collaborators and may be hesitant to escalate disputes due to potential future partnerships. The panel also touched on investment treaty protections and the implications of industrial policies on international arbitration.

Overall, the session underscored the dynamic and complex nature of arbitration in the life sciences sector, with a focus on the interplay between regulatory frameworks, IP protection,



and the evolving landscape of international collaboration. The discussion highlighted the necessity for legal practitioners in this field to be well-versed in both legal and industry-specific knowledge to effectively navigate potential disputes.

### **Authors**

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### **Topics**

Life Sciences, Arbitration

### **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

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very much to Allen &

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every and and the everyone

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that is sitting with me,

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I must say those things

00:00:15

about our moderator. This is

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a panel that was a

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visit first time that we

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have a paddle in life

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and Sciences in at Washington

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arbitration week. And this is

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mainly because of fox Patrick

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Pierce sales and Catering Flores

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initiative. We we we basically

00:00:36

thought we know what would

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be Innovative. What would be

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important in terms of growth

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of arbitration in a specific

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field? And there you go,

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they raise their hand. I

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said, well, we must have

00:00:49

a panel on light and

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Sciences because of the, the

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steps and the growth in

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in general, International commercial arbitration.

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But not only that investor

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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

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in. In that Washington d.c.,

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he has extensive experience, representing

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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

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US, state department for nearly

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a decade working on economic

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and natural resources, diplomacy and

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departed and departed as the

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chief of investment arbitration. In

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addition to his representations, Patrick

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was on a drafting committee

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for the revision of international

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Court of arbitration rules. And

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led the negotiations with several

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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

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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

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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.

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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

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you watching it in a

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recording, it is the Monday

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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

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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,

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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

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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

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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?

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Why does it matter how

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to clients Implement them in

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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

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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

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judge Hilton and has been

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counseled to the house committee

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on Energy and Commerce, where

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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

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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

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president for the federal government

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relations at the biotechnology industry

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organization, which has the great

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acronym bio, where he successfully

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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,

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does anyone call it that?

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Nailed it. That's, that's some

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acronym training, including important reforms

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of the accelerated approval pathway

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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

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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

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tend to require in international

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arbitration and to his right

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is a woman who probably

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needs no introduction to those

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of us in Washington, money

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cheek, Chicot, chairs, Covington's, International

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arbitration, practice and handles a

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wide variety of international commercial

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and investment, treaty matters. She

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also most impressed, most importantly,

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I also, most importantly, serves

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as counsel to Ukraine at

00:07:47

the international court of justice

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where she just received a

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very favorable ruling on provisional

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measures and is really doing

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international law, a great service

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and we thank her for

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that. Imani is experience with

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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

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where she's, of course a

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partner, she has handled high-profile

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investment treaty disputes and including

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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

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dispute settlement. Roster for the

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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

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about how those disputes happen.

00:09:11

Sure. Thank you very much

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and I hope you all

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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

00:09:55



work with Democrats and Republicans

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to ensure the predictability. It

00:10:00

is a major factor in

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also just ensuring that they

00:10:03

know what to expect when

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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

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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

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in a hundred years, pandemic,

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Really spur the interest of

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folks. As we have this

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conversation I can tell you

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generally. Another thing that life

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sciences companies care deeply about

00:11:01

is a resilient supply chain

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but also a redundant supply

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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

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vaccine. You need to have

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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

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to the United States, doesn't

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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

00:11:38  
not to say that we

00:11:39  
shouldn't be trying to do

00:11:40  
more in the United States.

00:11:42  
Because one thing the pandemic

00:11:43  
has shown us, is there

00:11:45  
a number of components to

00:11:46  
Therapeutics and vaccines and medical

00:11:48  
devices which were manufactured elsewhere?

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Really at endemic in a

00:11:53  
create shortages things that we

00:11:55  
do not want. But we

00:11:56  
know for a fact that

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the B Administration has taken

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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

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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

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subsequently did. And earlier this

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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

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felt formulations, they wanted to

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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

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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

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biotechnology and biomedical fractured executive

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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

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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

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dollars. I believe it is.

00:13:52

Yeah, to catalyze the establishment

00:13:54

of the best domestic and

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bio industrial manufacturing base. So

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all of this money is

00:14:00



going out the door to

00:14:02

bolster domestic manufacturing again, trying

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to bring things back to

00:14:09

the United States. At the

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same time, they're concerned regulatory

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tools, that FDA has been

00:14:14

employing to try to address

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shortages and try to encourage

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domestic manufacturer, one of which

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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

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cheaper to manufacture it, manufacturer

00:14:38

in the United States things

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like continuous manufacturing. 3D manufacturing

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certain types of other platform

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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

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ensuring to the greatest extent

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practicable. At the same time

00:15:07

to Congress has been spending

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a heck of a lot

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of time. Focused on this

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issue. And at the beginning

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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

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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

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medical technology and alike. How

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are user at least is

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federal government through the Medicare

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and Medicaid Program, VA Health

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defense, Health at cetera and

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some were saying while you

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can't government can't purchase unless

00:15:49

it's made that's entirely impracticable

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and fortunately ideas like that

00:15:54

or not or not, ultimately

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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

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and Senator Burr. Have a

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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

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it's called warm Ace manufacturing.

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That's under consideration right now.

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And again on both the

00:16:34

house and the Senate side

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there is a consideration of

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a pilot program on Advanced

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Manufacturing Technologies. We're in for

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the first time manufacturers were

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would be able to seek

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a designation that their technology

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itself divorce from the consideration

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of an application but rather

00:16:53

their technology could be designated

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so that in the future

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other third parties. Your license

00:16:59

with that, they license with

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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

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made with that technology, all

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under consideration right now. But

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I guess the punchline which

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and I've been repetitive, so

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you should get it is

00:17:14

the fact that while not

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on International arbitration itself impacting.

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It is the desire that

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many folks, many see how

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many lawmakers want to bring

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things back to the United

00:17:25

States. Not at the exclusion

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of international, but if future

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manufacturing capacity, thanks that's. That's

00:17:33

exceptionally helpful and I didn't

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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

dwelt, 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 AI'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 is 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 not so much

00:55:38



that you asked that's been

00:55:39

out in front their place,

00:55:41

great point because that has

00:55:45

been the case I can

00:55:46

say, and I spent time

00:55:48

on a hill and when

00:55:49

you're on the hell, you

00:55:49

think, you know, everything and

00:55:50

turns out, you don't know

00:55:51

anything. And then I went

00:55:52

to regulated industry at by

00:55:55

where I was to have

00:55:56

lobbyists at by when I

00:55:58



did get to meet with

00:55:59

a number of CEOs and

00:56:00

other leaders in the biotechnology

00:56:02

feel and just to underscore

00:56:03

the points that are being

00:56:05

made, nothing. I mean, the

00:56:09

lifeblood of our technology and

00:56:10

Life Sciences industry is intellectual

00:56:12

property. It's by far the

00:56:14

most important thing, it allows

00:56:15

you with strong Pattinson certain

00:56:17

pets to go out there

00:56:19

a tenth as well. FDA

00:56:21



granted the exclusivity. That's a

00:56:22

whole different things but you

00:56:23

know, that's another protection that

00:56:25

from FDA to not agree.

00:56:28

Edit the product, it generic

00:56:30

come product for certain. Of

00:56:32

time, but that's what allows

00:56:35

Life Sciences. Companies of all

00:56:38

sizes, go out and get

00:56:39

the capital that they need

00:56:40

to go down the path

00:56:42

of trying to commercialize the

00:56:45

product of the course of

00:56:46



10 15, 20 years and

00:56:48

these threats to Life Sciences.

00:56:50

Were they be the international

00:56:51

ones, Martis, mentions or, you

00:56:54

know, Mark and rights under

00:56:56

bidole act in the United

00:56:57

States, that abuse or threats,

00:57:00

which unfortunately come up every

00:57:05

now and then, which really

00:57:06

are of the greatest concerns

00:57:08

because the only way that

00:57:09

folks are going in the

00:57:10

best of billions of dollars

00:57:11



necessary to develop new Therapeutics

00:57:13

is with the assurance that

00:57:14

they can protect these from

00:57:16

competition for a. Of time.

00:57:18

And if you then have

00:57:19

whether the domestic US government

00:57:21

or international government saying that

00:57:23

during because his ex-wife That

00:57:29

really is chilling to investment

00:57:31

in life sciences. Well, I

00:57:33

like the the continued use

00:57:35

of Life blood since we

00:57:37

are talking about life sciences.

00:57:38



I mean, we did hear

00:57:39  
a lot about the kind

00:57:40  
of concerned about exclusivity. We

00:57:44  
haven't even invoked Waxman but

00:57:47  
we'll come back to that.

00:57:47  
Perhaps two things just to

00:57:49  
throw it on the table.

00:57:50  
So that folks can pick

00:57:51  
it up and talk about

00:57:52  
it is we haven't really

00:57:53  
spoken about generics in this

00:57:56  
in this space and the

00:57:58  
other thing we haven't really

00:57:58



chatted about is and I

00:58:01

know Marty can probably speak

00:58:02

to this too. Is that

00:58:04

the exclusivity periods? Or that

00:58:06

kind of Ip protections and

00:58:07

some of the multi-national big

00:58:10

regulatory big treaties, right? So

00:58:12

there was a lot of

00:58:13

criticism back when the United

00:58:14

States was a signatory of

00:58:17

the TPP about the, the,

00:58:19

the protection, that the United

00:58:21

States helped broker in the

00:58:23



IP space, and as one

00:58:25  
of the leading Innovative markets

00:58:27  
in the world, Probably a

00:58:29  
lot of your clients. Brent,

00:58:30  
we're not thrilled with with

00:58:31  
what the United States provided

00:58:33  
for, in that agreement. So

00:58:34  
we can, we can talk

00:58:35  
a little bit about that

00:58:36  
to let me just shift

00:58:38  
gears for a second and

00:58:40  
talk about Trade Secrets and,

00:58:44  
and go back to basics.

00:58:45



You are a lawyer to

00:58:47

go back to basics. And

00:58:50

those Basics are arbitration requires

00:58:53

Trivedi, right? And When someone

00:58:57

steals or is attempting to

00:58:59

steal your IP and there's

00:59:02

a trade secret issue, you

00:59:04

don't always have direct privity

00:59:06

with those with that person.

00:59:08

Like, I'm thinking about a

00:59:09

rogue employee or something else.

00:59:11

So how do we get

00:59:12

around those tricky? Little issues

00:59:14



in in the trade secrets

00:59:16

space. Anyone want to handle

00:59:18

that? These were not pre-planned

00:59:23

questions, if that's, if that's

00:59:24

too much of a stump

00:59:26

stumper, or it's improperly phrased

00:59:29

to let me know. Brent,

00:59:33

go first. There it is.

00:59:34

Haha. Okay, well that bought

00:59:37

enough time for the most

00:59:39

competent person on the panel

00:59:40

to answer it. In my

00:59:43

experience that hasn't actually really

00:59:46



been an issue in that

00:59:50

it's been kind of a

00:59:51

company to company. You know,

00:59:54

you stole our Trade Secrets

00:59:55

allegation. And even if it's

00:59:59

pinned on a date of

01:00:01

which specific, you know, actors

01:00:04

might have done. The, the

01:00:05

stealing really that the companies

01:00:09

are responsible for the actions

01:00:10

of their place. So it

01:00:11

hasn't actually, you know, manifest

01:00:14

itself. Now, what I could

01:00:15



see because of the interaction

01:00:18

between these International arbitration and

01:00:20

litigation is you could see

01:00:22

a situation where you know

01:00:24

company is just Company B,

01:00:26

you know, for because they're

01:00:30

Rogue employee, you know, torque

01:00:32

but the trade secrets of

01:00:33

company a and then left.

01:00:34

Start company C or something

01:00:36

like that. And Company B

01:00:38

is like a better Target.

01:00:39

You know, you could see

01:00:40



some then, parallel litigation where

01:00:42

Company B sues its former

01:00:44

employee. So I could spin

01:00:47

off into In two other

01:00:50

kind of parallel litigation tracks.

01:00:54

And I have seen, you

01:00:56

know, situations where again going

01:00:59

to the messiness of these

01:01:01

carve-outs where, you know, if

01:01:04

your have a trade secrets

01:01:05

litigation. But it it's really

01:01:06

kind of a patent dispute

01:01:08

disguised as a trade secrets

01:01:09



litigation, then, maybe one of

01:01:12

you could go to court

01:01:14

and get like a declaratory

01:01:15

judgment that you didn't infringe

01:01:16

the patent or something like

01:01:17

that, I would run in

01:01:18

parallel. So I think you

01:01:20

could have parallel litigation against

01:01:22

the Rogue employee. If that's

01:01:23

truly the case, I think

01:01:25

they then be knowledge. You

01:01:27

have to consult your patent

01:01:28

College. We have to consult

01:01:29



your employment law colleagues still.

01:01:32

Like, when you're responsible for

01:01:33

the Rogue employee, or whether

01:01:35

you're some kind of Defense,

01:01:35

I'm so I think it

01:01:37

could, it could play in

01:01:39

but I think it would

01:01:40

be litigated and contested issue

01:01:42

because in my experience is

01:01:44

the companies responsible for the

01:01:47

trade-secret theft in terms of

01:01:48

the allegations So but it

01:01:52

also, I guess the last

01:01:52



thing I would say is

01:01:53

if it is truly that

01:01:54

you know it may be

01:01:57

a dispute. That's resolved short

01:02:00

of completing the arbitration, the

01:02:03

parties, the best. You anticipated,

01:02:06

the exact fact that I've

01:02:08

litigated. I mean we had

01:02:09

a situation under a licensing

01:02:11

agreement that we allege there

01:02:13

was a patent infringement that

01:02:15

infringement case went forward in

01:02:17

the in the kind of

01:02:18



us courts. But in parallel

01:02:21

there was the possibility because

01:02:23

of the draft arbitration clause

01:02:24

in the licensing agreement to

01:02:25

bring a parallel arbitration on

01:02:27

different issues and it was

01:02:29

actually the threat of the

01:02:30

arbitration that resolves the overall

01:02:34

dispute because the Patton courts

01:02:36

were taking a while and

01:02:39

it's too high risk for

01:02:40

both parties to have a

01:02:42

disposition on on the patent.

01:02:45



At and the real issue

01:02:47

was the potential improper use

01:02:49

of of the, the product

01:02:51

under the licensing agreement, which

01:02:52

was resolved through the threat

01:02:54

of arbitration in an imminent

01:02:56

damage which was going to

01:02:57

go a lot quicker. So

01:02:58

arbitration is a tool in

01:03:01

the kind of, let's say,

01:03:04

more kind of prosaic litigation

01:03:07

strategy, that a lot of

01:03:09

our clients are going to

01:03:10



be interested in another. Another

01:03:12

question I had in this

01:03:14

one is I guess for

01:03:16

Peter and Marnie is she

01:03:21

mentioned ists or investment treaty

01:03:23

protections. What are the compulsory

01:03:26

licenses is certainly one of

01:03:27

them but what are the

01:03:28

other kinds of State actions

01:03:30

that could give rise to

01:03:31

a dispute in this space?

01:03:34

Just kind of throw some

01:03:35

of those out on the

01:03:36



table. Yeah, well in the

01:03:39

NAFTA, dispute between Lily and

01:03:42

Canada, it had to do

01:03:44

with the failure to provide

01:03:46

patent protection, in accordance with

01:03:49

International standards in the standards

01:03:51

that are in the the

01:03:52

treaty. It also can be

01:03:54

on the new regulatory side

01:03:57

where the country's regulatory approval

01:04:03

to generics for products that

01:04:06

are still protected by patents

01:04:08

and the interplay between the

01:04:10



IP protections and the Regulatory

01:04:14  
and data exclusivity protections there.

01:04:18  
And you know I can

01:04:21  
as I said for me

01:04:23  
and my experience some of

01:04:26  
the investment treaty issues really

01:04:28  
are when I pee kind

01:04:31  
of bleeds over into industrial

01:04:32  
policy. So you know, if

01:04:34  
there is a domestic Champion

01:04:37  
that a company Are there

01:04:39  
a country or their regulatory

01:04:41  
authorities are trying to help

01:04:43



particularly say? I know a

01:04:45

generic company that would like

01:04:47

to have access to some

01:04:48

of the IP information that

01:04:51

the government has a because

01:04:53

of the regulatory approval process.

01:04:55

Then there could be some

01:04:57

misuse of that intellectual property

01:05:01

that also could run afoul

01:05:02

of investment treaty protection. So

01:05:06

those are just some of

01:05:07

the issues that come to

01:05:10

mind, but you also I

01:05:11



know have arbitrator in this

01:05:13

area. So my father's other

01:05:15

thought, well, I just just

01:05:16

kind of 12 finger follow

01:05:17

up on that. Do you

01:05:19

see? Did you see governments

01:05:22

laying claim to too? Kind

01:05:25

of some of the defenses

01:05:27

that they might have with

01:05:28

regard to public policy essential

01:05:31

security card balance during pandemic

01:05:32

things like that playing more

01:05:33

ascendant role in in investment

01:05:36



disputes or do you mean

01:05:39

industrial industrial policy tool? Sounds

01:05:41

like a claimant's Prayers. If

01:05:45

you were representing the government,

01:05:47

you could say, well this

01:05:48

is a matter of public

01:05:49

policy and public health, and

01:05:50

therefore it's not covered under

01:05:51

the treaty. So I think

01:05:54

the public policy exception, I

01:05:55

mean that would be my

01:05:56

go to its public health

01:05:58

of its public policy and

01:06:00



that is a go-to for

01:06:01

many governments and I think

01:06:02

you know, it's going to

01:06:03

be it's an arbitrator's job

01:06:05

to try to sort through,

01:06:07

you know, what is a

01:06:09

legitimate public policy exception and

01:06:12

what is not. So I

01:06:14

think yes, like that's an

01:06:15

issue that we'll get litigated

01:06:17

in almost any life sciences

01:06:20

related, investment treaty to spew

01:06:23

in my view because it's,

01:06:24



that's available to say, like,

01:06:26

what we needed to do

01:06:26

this because it's in the

01:06:27

public interest. But I think

01:06:29

that that is really the,

01:06:30

the beginning of a conversation

01:06:33

and scrutiny by the arbitrators,

01:06:35

and not really an endpoint,

01:06:37

because there may have been

01:06:39

other ways to go about

01:06:40

it, you know, was it

01:06:42

done in a manner consistent

01:06:43

with Weather IP obligations and

01:06:46



international IP Norm. So I

01:06:48  
think it it's kind of

01:06:50  
it's a starting place but

01:06:51  
not really the ending bending

01:06:52  
place. That would be, that

01:06:54  
would be my view and

01:06:55  
National Security. We can all

01:06:59  
probably have an opinion on

01:07:00  
that, but in my mind

01:07:01  
it's not a good fit

01:07:02  
for this situation. I guess

01:07:05  
I would just like Omar

01:07:06  
knees, and same to you.

01:07:07



We have that. We had

01:07:08

a case where involving, a

01:07:09

taking of a distribution Network

01:07:11

and absolutely. The first offense

01:07:13

was public health, it's in

01:07:15

the, it's in the public

01:07:16

good. That may be an

01:07:18

easier argument to make, when

01:07:19

you're talking about a, you

01:07:21

know, media James here is

01:07:22

gene therapy center or the

01:07:24

side of us that we

01:07:25

have the clinical trial and

01:07:27



it was, it was a

01:07:30

bit more difficult than, in

01:07:31

that case that the arbitrator's

01:07:33

we're, we're fairly concerned about

01:07:35

the legitimacy of a public

01:07:37

policy. I mean, is it

01:07:41

public policy to try to

01:07:43

on Shore or Force Supply?

01:07:45

Chains back back on tour

01:07:47

in a there could be

01:07:48

damaged there to to those

01:07:49

folks who can do it

01:07:50

with better margins offshore and

01:07:53



now we're being forced it

01:07:54

to move forward. So let

01:07:57

me, let me see. We

01:07:58

have about 10-15 more minutes,

01:07:59

folks in the audience had

01:08:02

any questions. Don't be bashful.

01:08:05

Yes, please. If you could

01:08:06

just, we could get you

01:08:08

a microphone. We have to

01:08:11

use this one. Sorry. Thank

01:08:17

you for this bike. So

01:08:19

thank you. Thank you for

01:08:21

this morning has been wonderfully

01:08:27



or an introduction to that

01:08:29

topic. Forgive my ignorance, why?

01:08:32

What is the purpose of

01:08:33

carving out patent disputes in

01:08:36

the dispute. Resolution close. Peter

01:08:42

gave me the mic. Background

01:09:37

background. Mike's on, but they

01:09:43

can hear us at home

01:09:44

too, so that's good. Okay.

01:09:46

And I can protect so,

01:09:48

so so in my mind,

01:09:50

you know, that is one

01:09:52

of the issues, its predictability,

01:09:53



I'm its expertise. It's the

01:09:56

fact that you have relied

01:09:58

on your, for, your US

01:10:00

Patent. You know, you've relied

01:10:01

on a certain set of

01:10:03

us standards and it kind

01:10:06

of happened to your product

01:10:07

at its. Unless you, you've

01:10:10

decided you're going to have

01:10:11

like three pain experts, as

01:10:16

your arbitration panel who will

01:10:18

be applying US law. There's

01:10:19

some risk. There's also no

01:10:20



chance of appeal and to

01:10:22

use our favorite phrase, the

01:10:24

lifeblood of these companies is

01:10:26

IP. A lot of General,

01:10:29

counsel's are quite wary of

01:10:32

there. Being no appeal process

01:10:34

with regards to litigating a

01:10:37

patent. So that that's in

01:10:38

my experience. I'm sure. Observations

01:10:43

very consistent, even in the

01:10:44

US. If you just look

01:10:46

at litigation, there's a remarkable

01:10:48

amount of that at the

01:10:49



circuit court level of overruled

01:10:53

Ip decisions. And it's often

01:10:55

the case that when were

01:10:56

involved in a dispute from

01:10:58

the start, the parties know

01:11:00

that they're really positioning themselves

01:11:01

for a later trial because

01:11:03

in the first instance, they

01:11:04

have a judge who isn't

01:11:05

burst in the architecture of

01:11:06

Ip law and all the

01:11:08

intricacies of the IP issues.

01:11:09

And so they're really establishing

01:11:11



a record and I think

01:11:13

you see the same thing

01:11:13

in arbitration. It's really difficult

01:11:15

you know speak about finding

01:11:20

arbitrators to both have the

01:11:22

subject matter knowledge to arbitrate

01:11:24

these disputes are free of

01:11:27

any kind of encumbrances that

01:11:29

would make it inappropriate for

01:11:30

them to hear them. And

01:11:31

then you want them to

01:11:32

be IP experts on top.

01:11:33

That's that's a very, very

01:11:35



tall order and you might

01:11:37

be able to find three

01:11:37

people and they might be

01:11:38

able to schedule you in

01:11:39

a two and a half

01:11:40

years from now. You get

01:11:42

the tents to really be

01:11:45

a potential drag on on

01:11:47

the arbitration process. Not that

01:11:49

I think it's a walk

01:11:50

in the park trying to

01:11:50

run a parallel arbitration with

01:11:53

an with an IP carve

01:11:54



out some time in for

01:11:56

investment treaty arbitration. And also

01:11:57

want, probably those arbitrators to

01:11:59

have some familiarity with public

01:12:00

international law and how to

01:12:01

read a treaty. So later

01:12:03

that on top two of

01:12:04

you were looking to be

01:12:05

a unicorn in the space.

01:12:07

Now, you know what, you

01:12:08

need to get expert on

01:12:09

and then you'll get appointment.

01:12:10

Other other questions from the

01:12:12



audience. Set the mic on

01:12:17

the table. You might not

01:12:18

hear it in the room

01:12:19

but it is coming through

01:12:20

at home. So if you

01:12:20

can hear us, then we

01:12:21

can use the mic on

01:12:22

the table. Thank you very

01:12:25

much for all the enlightenment

01:12:28

that you have provided. I

01:12:29

had a thought concerning what

01:12:34

is becoming or has become

01:12:35

a trend with respect to

01:12:37



to trade at which is

01:12:40

trying everyone, perhaps let buy

01:12:42

it by the us at

01:12:43

some stage, but everyone is

01:12:44

really trying to bring production

01:12:46

on Shore and and somehow

01:12:50

require National produce or or

01:12:55

input sensor. And that made

01:12:56

me think about the performance

01:12:58

requirements that are in various

01:13:01

free trade agreements. Mostly had

01:13:04

those that by the us

01:13:05

but in general in free

01:13:06



trade agreements. We don't we

01:13:07

don't have performance requirements in

01:13:11

necessarily in the old model

01:13:14

bilateral. Entreaties. And, and, and

01:13:17

that made me think whether

01:13:18

or not for Life Sciences,

01:13:20

because be sure of whether

01:13:22

you going to produce on

01:13:24

Shore or elsewhere. In the

01:13:26

our time that Tetra comes

01:13:28

to mind whether the network

01:13:31

of investment treaties including fdsfds

01:13:34

generally do but but those

01:13:36



are not most of the

01:13:37

bilateral investment treaties, whether the

01:13:40

network network of investment treaties

01:13:42

is Israeli. ready or or

01:13:47

provides the tools to prevent.

01:13:53

Did the performance requirements that?

01:13:56

Why would she be in

01:13:57

in another, in in free

01:14:00

trade agreements and whether that

01:14:01

is a rather than issue

01:14:04

for Life Sciences. So any

01:14:07

any takers on that? I

01:14:09

do think that the majority

01:14:12



of markets where you have

01:14:16

let you know this question

01:14:19

posed, whether it be as

01:14:21

an Innovative Market or Market

01:14:23

are in some ways at

01:14:24

this point. Covered under one

01:14:26

of the larger ftas, as

01:14:28

the spaghetti Bowl goes and

01:14:30

the end of the clever

01:14:31

use of for greater certainty

01:14:33

retroactively, perhaps cover some of

01:14:37

the first and second-generation bits.

01:14:39

I'm not sure if that's

01:14:40



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

01:14:42

an absolutely good point. I,

01:14:44

I, I, I am not

01:14:46

aware of the 20 cases,

01:14:48

that, Peter mentioned that, that,

01:14:51

that question is, is But

01:14:54

I do think that one

01:14:55

of the interesting things will

01:14:56

be how robust some of

01:14:57

those FDA is that that

01:14:59

include some of these Innovative

01:15:01

Concepts retroactively work backwards to

01:15:05

handle, some of the less

01:15:07



robust B. But I mean

01:15:09

this this goes to a

01:15:10

larger discussion about whether 1st

01:15:13

and 2nd generation, bilateral investment,

01:15:14

treaties are going to survive

01:15:15

over the next 10 years.

01:15:16

Might my own suggestion is

01:15:18

that it will be very

01:15:19

difficult for them to persist,

01:15:20

but that's just my view

01:15:21

Barney. take, take take this

01:15:25

one with some Okay, we've

01:15:30

got the better microphone now,

01:15:31



I agree. It's a very

01:15:34

good question. I mean, I

01:15:35

think gone older B. It

01:15:37

really might depend on how

01:15:38

it's implemented because you could

01:15:40

see it be implemented in

01:15:42

a way that could give

01:15:43

rise to some kind of

01:15:45

national treatment around my phone

01:15:46

claim or maybe it's implemented.

01:15:49

Like, in a very kind

01:15:50

of arbitrary way. So in

01:15:52

my mind and maybe also

01:15:54



for older generation B, I

01:15:56

think there's a question. Is

01:15:57

there a Gap? Or maybe

01:16:00

depending on how it's implemented?

01:16:02

You could still do something,

01:16:04

but I do think that

01:16:06

To your point. I mean

01:16:08

right now this idea like

01:16:10

onshoring as part of an

01:16:12

industrial policy after it is

01:16:13

something that everyone's doing and

01:16:15

I don't think I got

01:16:16

another face of it. That

01:16:17



itself would be a treaty

01:16:19

violation. But I do think

01:16:20

to your point like, well

01:16:22

how you do it, you

01:16:24

need to be thinking about

01:16:25

these International obligations, and I'm

01:16:28

sure Brent can a test

01:16:30

from a Time on the

01:16:31

bill, whenever our Congress is,

01:16:33

considering are these types of

01:16:35

Provisions are. There's usually plenty

01:16:37

of people up there kind

01:16:39

of whispering in the ears

01:16:39



of folk saying, you know,

01:16:41

hey, the US has a

01:16:42

lot of international agreements topic

01:16:44

that you probably should consider

01:16:46

as your drafting or legislation.

01:16:47

So, I imagine there's a

01:16:49

way to do it. That's

01:16:50

consistent with those obligations, but

01:16:53

there's probably also wasted you

01:16:54

at that would be inconsistent.

01:16:55

And bring can tell us

01:16:57

how, how well-received there that

01:16:59

the statement to Congress, there

01:17:01



are a lot of International

01:17:02

Airport received that phrases. Oh

01:17:07

yeah, there was like oh

01:17:07

okay well then we won't

01:17:08

touch it as well. Any

01:17:13

other questions from the audience?

01:17:16

Does a question online? Excellent.

01:17:19

Jose Antonio, would you like

01:17:21

to to to be our

01:17:23

online? The face of the

01:17:25

online community. Show the questions

01:17:37

from Laura Richardson, and it's

01:17:40

to Peter. So, there you

01:17:42



go. Given the difficulties and

01:17:44

inherent speculation required in quantifying

01:17:47

Damages in life sciences. Dispute,

01:17:49

has there been any consideration

01:17:52

or attempt to include liquidated?

01:17:55

Damages Clauses in life sciences,

01:17:57

commercial collaboration agreements for breaches

01:18:00

of certain terms and parentheses

01:18:02

such as are common in

01:18:05

construction agreement, or there's a

01:18:08

second question or are their

01:18:11

unique features in the Life

01:18:13

Sciences field, that wouldn't would

01:18:15



not lend itself to liquidated

01:18:17

damages causes That's an excellent

01:18:21

question. Well well, he's getting

01:18:23

a microphone. I'm sure French

01:18:24

are well-versed in liquidated. Damages

01:18:26

Clause is speaking of kind

01:18:28

of cross, cultural conflict, between

01:18:29

innovators in other jurisdictions. Now

01:18:31

that you have found that

01:18:32

was why I can't speak

01:18:35

to the universe but only

01:18:37

infrequently come across attempts to

01:18:39

introduce the concept of liquidated

01:18:41



damages within a life sciences

01:18:43

contact. I think the challenges

01:18:45

are typically that if you

01:18:48

takes a trade secret misappropriation,

01:18:50

where are you? You for

01:18:53

some of your .45 protocols

01:18:55

or are they may be

01:18:57

at being expropriated, they're still

01:19:00

value and the company doesn't

01:19:02

want liquid ant baits. What

01:19:04

they want is to continue

01:19:05

the development of their products

01:19:06

and usually 2 to block

01:19:10



the party. This Miss appropriate

01:19:12  
the assets in. So it's

01:19:15  
often the case that we

01:19:16  
find ourselves in a little

01:19:17  
bit of a difficult situation

01:19:18  
where we are To assess

01:19:21  
damages with the hope that

01:19:22  
it's irrelevant because the real

01:19:24  
goal of their arbitration is

01:19:26  
to secure the IP to

01:19:28  
secure the path forward and

01:19:29  
to ensure that the kind

01:19:33  
of ancillary roads to investment

01:19:35



remain open. And I think,

01:19:36

maybe maybe that's the key.

01:19:38

Is that, you know, those

01:19:39

in life sciences, know that

01:19:41

the product that comes to

01:19:42

Market sometimes Bears, a resemblance

01:19:44

to what you thought you'd

01:19:46

bring 20 years ago. But

01:19:47

often the case, it's that

01:19:50

along the path. You found

01:19:53

other opportunities, other therapeutic categories,

01:19:55

other aspects of the product

01:19:58

to be developed so that

01:19:59



you have a therapy that

01:20:00

still valuable to patients, still

01:20:03

commercially viable, but not exactly

01:20:05

where you thought you'd end

01:20:06

up. And, and the question

01:20:08

of whether the promised utility

01:20:10

is, is needs to be

01:20:12

specified, has been litigated in

01:20:14

in our space right now.

01:20:15

I would just add that

01:20:17

to Peter's point. I have

01:20:19

clients who start Down who

01:20:22

acquired assets which are decades-old

01:20:26



protections for the indication and

01:20:30  
the like, but like I

01:20:31  
could think of on which

01:20:32  
was a weight loss drug,

01:20:33  
which ultimately was brought to

01:20:34  
the market for Pediatric epilepsy.

01:20:37  
You just never know where

01:20:39  
the science is going to

01:20:40  
lead you with products. We

01:20:44  
have time for one more

01:20:45  
question, don't be, don't be

01:20:47  
shy. Anything else online? One

01:20:52  
more question. It's David Engel

01:21:00



from a delivery. Thank you

01:21:01  
for the panel, just a

01:21:02  
question on potential threats to

01:21:04  
to Life Sciences. It seems

01:21:07  
to make more this requires

01:21:09  
billions of dollars to invest

01:21:10  
it in the night and

01:21:11  
I did it extremely likely

01:21:13  
to fail. I'm I'm actually

01:21:15  
it's much easier to to

01:21:16  
get financing to commit financing.

01:21:18  
This idea when your monetary

01:21:20  
environment, where is 11 Crest

01:21:23



Drive? Liquidity. Sloshing around in

01:21:25

also with your interest rate

01:21:27

environment, flat is the present

01:21:29

value of potential profits in

01:21:31

twenty years time as we

01:21:33

have to move out of

01:21:34

that era. When money is

01:21:35

little more expensive and we

01:21:37

didn't get those advantages, is

01:21:39

that a huge threat. I'll

01:21:40

be going to see a

01:21:41

reduction in innovation in the

01:21:43

future. I don't say so,

01:21:46



Is that a possibility that

01:21:47  
they'll be far more disputes?

01:21:48  
And typically we think when

01:21:49  
it's less money sloshing around,

01:21:51  
people, get paid for their

01:21:52  
respects to get paid, something

01:21:54  
you get dispute. So is

01:21:55  
that a threat? Would I

01:21:56  
have to cut everybody off

01:21:57  
but I'm asking about 20,

01:21:59  
no. We start with some

01:22:01  
litigations and let me just

01:22:07  
start with, thank you. It's

01:22:10



not, it's not going to

01:22:12

be good for the US

01:22:13

government for the research and

01:22:17

development into new therapies vaccines

01:22:20

and the like by implementing

01:22:23

on the number to Rexburg

01:22:26

e r. A first a

01:22:28

price setting of a of

01:22:30

a maximum fair price for

01:22:33

a product. And then a

01:22:34

negotiation downward on that price

01:22:37

which is going to be

01:22:39

which is what is mandated

01:22:41



by the inflation reduction act

01:22:43

that the pharmaceutical industry to

01:22:45

biotechnology industry were very concerned

01:22:48

very opposed to the notion

01:22:51

that the government can be

01:22:52

directly negotiating on a subset

01:22:54

of very important Therapeutics and

01:22:55

they contend and I agree

01:22:57

with them that this is

01:22:58

going to be too, unfortunately,

01:23:00

less. Development. I've already seen

01:23:02

one company indicate that they're

01:23:04

not pursuing an indication which

01:23:06



they, otherwise would because they

01:23:08

did not want to potentially

01:23:10

in the number of years,

01:23:11

be subject to direct negotiation

01:23:13

with new play. Some reduction

01:23:14

act calls for so that

01:23:16

is of of great concern

01:23:19

to a life sciences community.

01:23:21

I absolutely agree with French,

01:23:24

in the, in, in the

01:23:25

short-term, Mark conditions, change economic

01:23:28

conditions, change investment in life,

01:23:30

sciences remains relatively stable, in

01:23:33



light of your economic factors.

01:23:35

What what really kills investment

01:23:37

is significant outside action, anything

01:23:40

that that chills the investment

01:23:42

opportunity or or you know

01:23:44

people who invest in life

01:23:45

sciences know they're playing a

01:23:46

long game. What they're concerned

01:23:48

about is the time consistency

01:23:50

problem of some significant change

01:23:52

while they're kind of waiting

01:23:53

for the fruits of that

01:23:54

investment. All that said it

01:23:57



is certainly true. Your second

01:23:58

question it is always the

01:24:00

case that we see an

01:24:01

uptick in disputes when economic

01:24:03

conditions get tight you know

01:24:06

back in 2018 and it's

01:24:09

hard to remember that. There

01:24:10

was a downturn economically before

01:24:12

the pandemic, which kind of

01:24:13

stole the headlines but they

01:24:15

said that was the most

01:24:15

recent example, we saw where

01:24:17

the economy tightened up and

01:24:19



suddenly partners with whom you

01:24:20

were, you were quite High.

01:24:21

The forge ahead with now

01:24:24

you're looking at a stance

01:24:25

and and we see an

01:24:29

uptick in arbitration, we see

01:24:31

an uptick in patent disputes

01:24:33

and we see a large.

01:24:34

I'll take you in competition

01:24:36

claim where everybody's looking for,

01:24:39

you know, some other Revenue

01:24:42

stream or a way to

01:24:44

reduce kind of an ongoing

01:24:46



cost line. Well, we are

01:24:54  
at time at, so let

01:24:56  
me Falls to me to

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

01:25:00  
coffee and lunch and that

01:25:01  
will be served outside to

01:25:02  
directly after this panel. But

01:25:04  
secondly, to thank this incredible

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

01:25:11  
into life sciences and how

01:25:12  
they make late to the

01:25:13  
arbitration and thank you to

01:25:14  
you our audience at home

01:25:16



and here for your patience.

01:25:18

And of course again to

01:25:19

Jose Antonio, for inviting us.

01:25:21

Also, thank you very much.

00:00:02

Washington arbitration week. I will

00:00:05

make this very, very short

00:00:06

apart from saying thank you

00:00:08

very much to Allen &

00:00:09

every and and the everyone

00:00:11

that is sitting with me,

00:00:12

I must say those things

00:00:15

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

00:00:28

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.

00:00:59

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

00:01:12

at Alan. The warrior ovary

00:01:14

in. In that Washington d.c.,

00:01:16

he has extensive experience, representing

00:01:18

parties international disputes and providing

00:01:22



strategic advice on asset protection,

00:01:24

Global investment and Commercial contract.

00:01:27

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

00:01:38

departed and departed as the

00:01:40

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

00:01:54

Court of arbitration rules. And

00:01:56

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.

00:02:09

And the US China, bilateral

00:02:11

investment treaty, he has received

00:02:15

several Awards and serves as

00:02:16

served on multiple boards. He's

00:02:21

also an Adjunct professor at

00:02:23

Georgetown. He has a being

00:02:25

in several or he's part

00:02:28

of several arbitration centers. And

00:02:30



that lately has also being

00:02:32

involved in a various ever

00:02:35

presentations related to thank you

00:02:40

and with you or moderate.

00:02:42

Thanks, Jose. Antonio, I think

00:02:44

this is working. Welcome to

00:02:46

everyone in the room and

00:02:48

online. I really appreciate you

00:02:51

turning in the Monday after

00:02:53

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

00:02:58



and we're very grateful for

00:03:00

everyone to be. Here. We

00:03:00

have a a what we

00:03:04

hope is a pretty exciting

00:03:05

hour and 10 minutes or

00:03:06

so, for you today we're

00:03:09

going to be talking about

00:03:10

life sciences and for those

00:03:12

of you who are a

00:03:14

little bit confused or questioning,

00:03:17

what, what is, what our

00:03:18

life sciences, what is life

00:03:19

sciences? How does it work?

00:03:20



International arbitration. That's the purpose

00:03:22  
of the panel. So thank

00:03:23  
you, Jose Antonio for your

00:03:25  
invitation to us. All Washington

00:03:28  
arbitration week has become a

00:03:30  
can't-miss moments on the arbitral

00:03:32  
calendar and your willingness to

00:03:35  
pursue new areas that have

00:03:37  
not been discussed. Has is

00:03:38  
very much appreciated in life

00:03:39  
sciences is one of those.

00:03:40  
He mentioned Jose Antonio mentioned

00:03:43  
growth. The reason we're here

00:03:45



is because we see Life

00:03:47

Sciences as a particularly important

00:03:50

growth area and international arbitration

00:03:53

something on the order of,

00:03:56

we are just starting to

00:03:57

get some statistics on this

00:03:59

around, a quarter of cases,

00:04:00

currently in that the ICC,

00:04:04

for example, relate to some

00:04:06

IP issues. So, that that's

00:04:09

pretty significant, that a quarter

00:04:10

of the cases right now,

00:04:11

have IP a Jason or

00:04:13



IP related issues. I think

00:04:15

that is only going to

00:04:16

continue. So we're going to

00:04:18

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

00:04:29

with us, we have the

00:04:31

experts as Jose Antonio said,

00:04:32

Washington arbitration week likes to

00:04:35

call on the experts and

00:04:36



now we have them. So,

00:04:37

to my immediate right is

00:04:39

Brent them. Auntie, he serves

00:04:41

as the co-head of Life

00:04:42

Sciences at at BGR group.

00:04:45

He represents clients, particularly in

00:04:47

life sciences, companies to help

00:04:49

them achieve their objectives. With

00:04:51

regard, to the federal government,

00:04:52

to US federal government. He's

00:04:54

worked for Senator Warner, representative

00:04:58

Li Li, he clerked for

00:05:00

judge Hilton and has been

00:05:03



counseled to the house committee

00:05:04

on Energy and Commerce, where

00:05:06

he had responsibilities over Food

00:05:08

and Drug related issues. He

00:05:10

oversaw the empty enactment of

00:05:12

several laws, which I don't

00:05:14

fully understand, but I will

00:05:17

read them. Medical user fee

00:05:19

act, the project, bioshield Act,

00:05:23

and the reauthorization than this

00:05:24

one, I do know about

00:05:25

best Pharmaceuticals for children Act

00:05:27

and the prescription drug user

00:05:29



free act. The Padova pdufa

00:05:33

is also a senior vice

00:05:35

president for the federal government

00:05:37

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,

00:05:46

legislation more therapeutic project, Discovery

00:05:50

tax, credit liability protections for

00:05:52

bioterrorist in pandemic. Countermeasures to

00:05:55

reauthorization of the other law

00:05:57

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

00:06:09

and 21st century cures initiative.

00:06:13

So talking to his right

00:06:16

is Dr. Peter Rankin, he's

00:06:20

a PhD Economist and life's

00:06:23

and chairs, the life sciences.

00:06:24

Practice at Charles River Associates

00:06:26

for more than 20 years,

00:06:27

you've provided economic analysis and

00:06:29

opinion involving disputes involving pharmaceutical

00:06:33



biotechnology and medical device manufacturers.

00:06:35

He is offered public and

00:06:38

proprietary policy evaluation projects involving

00:06:42

Health Care reform. Reimbursement, methodologies

00:06:44

antitrust, exemption research and development

00:06:47

initiatives and research productivity. These

00:06:50

are these are maps. That's

00:06:52

that's part. And parcel of

00:06:54

Life Sciences, big words, he's

00:06:56

served as an expert in

00:06:57

litigation and arbitration which is

00:06:59

how we know him. He's

00:07:00

testified many times before Congress.

00:07:02



In arbitral disputes, he's often

00:07:04

retained to access to access

00:07:06

the breakdown development of commercial

00:07:08

and commercialization agreement. And he

00:07:11

has analyzed scores of agreements

00:07:14

in the Life Sciences industry.

00:07:15

That's what he'll be talking

00:07:17

about today and Hill. Discuss

00:07:18

those terms and what they

00:07:20

tend to require in international

00:07:22

arbitration and to his right

00:07:25

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

00:07:33

arbitration, practice and handles a

00:07:35

wide variety of international commercial

00:07:37

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

00:07:49

very favorable ruling on provisional

00:07:52

measures and is really doing

00:07:54

international law, a great service

00:07:56



and we thank her for

00:07:58

that. Imani is experience with

00:07:59

life sciences disputes. However, dates

00:08:02

back to her time, as

00:08:03

associate counsel at the office

00:08:04

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

00:08:17

dispute in. STS v e

00:08:19

l, i Lilly versus Canada

00:08:20



case, where she represented, Eli

00:08:23

Lilly and has successfully arbitrated

00:08:25

disputes under Life Sciences agreements,

00:08:27

including a 1.8 billion dollar

00:08:30

trade secret claim, which will

00:08:32

hopefully hear a little bit

00:08:33

more about. She is among

00:08:35

many boards and Association member

00:08:40

of the Council on Foreign

00:08:41

Relations and is on the

00:08:42

dispute settlement. Roster for the

00:08:44

Central, American Free, Trade Agreement

00:08:45

and the Korean Us free

00:08:49



trade agreement. So, Experts, if

00:08:52

you didn't get that, that's

00:08:53

the headline. So let's let's

00:08:54

start with, with, Brent, Brent.

00:08:57

I wonder if you could

00:08:58

kind of set the scene

00:09:00

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

00:09:13  
and I hope you all

00:09:14  
can hear me and I

00:09:15  
hope this is a very

00:09:16  
informal setting, which I appreciate

00:09:18  
I would say, let's have

00:09:20  
a good conversation, give me

00:09:21  
a squirrel. Then what did

00:09:22  
I bring notes to a

00:09:23  
conversation? And I would just

00:09:25  
know that I frequently do

00:09:26  
that with my wife is

00:09:27  
well I'm about to head

00:09:30



to the health and Life

00:09:32

Sciences. Practice at the B&G

00:09:33

are grouped. We have the

00:09:35

Good Fortune of representing a

00:09:36

number of innovative good drug

00:09:39

biologic, Medical Technology medical device

00:09:41

manufacturers. We have some insight

00:09:44

into what they are looking

00:09:46

for generally and that is

00:09:48

of course, predictability and fair.

00:09:50

In the regulation of their

00:09:52

products baleen in but they

00:09:55

work with Democrats and Republicans

00:09:57



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

00:10:05  
am a former FDA council

00:10:08  
at the end, house Energy

00:10:09  
and Commerce. I have a

00:10:10  
different take and viewpoint but

00:10:12  
I think it's pertinent to

00:10:13  
the discussion that we're going

00:10:14  
to be having today about

00:10:15  
International arbitration. Because what we've

00:10:20



been seeing recently is the

00:10:22

push on the behalf of

00:10:23

many lawmakers to have and

00:10:27

and and to have things

00:10:28

more or less internationally focused

00:10:31

and more domestically focused in

00:10:34

terms of our supply chain,

00:10:35

there was a tremendous re-examination

00:10:38

of the supply chain as

00:10:40

we headed into the pandemic,

00:10:41

there have been voices out

00:10:43

there for some time who

00:10:44

ever heard of a look

00:10:46



at the supply chain, but

00:10:47

I tell you a once

00:10:49

in a hundred years, pandemic,

00:10:50

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

00:11:04

but also a redundant supply

00:11:05

chain because whether it be

00:11:07

a pandemic or a natural

00:11:09

disaster or just a breakdown

00:11:12



at a facility, which is

00:11:14  
of great importance to production

00:11:16  
of a certain therapeutic or

00:11:17  
vaccine. You need to have

00:11:19  
supply chain supply chain with

00:11:21  
many different components to it.

00:11:24  
So, the notion of, well,

00:11:26  
let's just bring everything back

00:11:28  
to the United States, doesn't

00:11:30  
make sense because you need

00:11:32  
to be located in very

00:11:33  
many different places to ensure

00:11:35  
resilience and redundancy. Now, that's

00:11:38



not to say that we

00:11:39

shouldn't be trying to do

00:11:40

more in the United States.

00:11:42

Because one thing the pandemic

00:11:43

has shown us, is there

00:11:45

a number of components to

00:11:46

Therapeutics and vaccines and medical

00:11:48

devices which were manufactured elsewhere?

00:11:50

Really at endemic in a

00:11:53

create shortages things that we

00:11:55

do not want. But we

00:11:56

know for a fact that

00:11:58

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

00:12:08

early on in the bottom

00:12:09

presidency commanded, a number of

00:12:12

different agencies and departments to

00:12:15

give a look at the

00:12:16

supply chain. It was America

00:12:18

Supply chains was the name

00:12:19

of the executive order and

00:12:21

HHS was told to look

00:12:23

at pharmaceutical and medical device

00:12:25

and vaccine resiliency, which they

00:12:28



subsequently did. And earlier this

00:12:31

year, they reported back and

00:12:34

they talk about the types

00:12:36

of Investments, which have been

00:12:37

made during the pandemic of

00:12:38

more than four billion dollars

00:12:39

to help the manufacturing of,

00:12:42

you know, Whether it be

00:12:45

API, active, pharmaceutical ingredients ingredients,

00:12:50

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.

00:13:02

And they did put out

00:13:04

billions of dollars. And frankly,

00:13:06

they were pretty wise Investments,

00:13:09

so that has been going

00:13:12

on a dish sling. Earlier

00:13:15

this year the Biden Administration

00:13:18

put out an executive order,

00:13:19

I was focused in some

00:13:21

part of his entitled advancing

00:13:26

biotechnology and biomedical fractured executive

00:13:29

order. And what they did

00:13:31

is they commanded White House

00:13:33



to have a series of

00:13:35

meetings between industry and Regulators

00:13:39

to talk about what more

00:13:41

could be done. And as

00:13:43

part of this executive order,

00:13:45

they told the Department of

00:13:47

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

00:14:25

have an office at the

00:14:26

FDA, the emerging Technologies program,

00:14:28

which is looking at these

00:14:30

Technologies, which make it cheaper

00:14:33



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

00:14:44

certain types of other platform

00:14:47

Technologies which which can provide

00:14:50

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.

00:14:59

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

00:15:08

a heck of a lot

00:15:09

of time. Focused on this

00:15:12

issue. And at the beginning

00:15:13

of the pandemic, there were

00:15:15

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.

00:15:30

You can't sell to know

00:15:31

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

00:15:41

and Medicaid Program, VA Health

00:15:43

defense, Health at cetera and

00:15:47

some were saying while you

00:15:48

can't government can't purchase unless

00:15:49

it's made that's entirely impracticable

00:15:51

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

00:16:16

right now. Which would empower.

00:16:19

The federal government to set

00:16:21

aside certain manufacturing rights in

00:16:25



the case of a pandemic

00:16:26

it's called warm Ace manufacturing.

00:16:30

That's under consideration right now.

00:16:32

And again on both the

00:16:34

house and the Senate side

00:16:35

there is a consideration of

00:16:36

a pilot program on Advanced

00:16:40

Manufacturing Technologies. We're in for

00:16:42

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

00:17:03

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

00:17:37

four-year. Now, he's now we

00:17:38

know and we can we

00:17:39



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

dwel, 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 AI'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 is 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 not so much

00:55:38

that you asked that's been

00:55:39



out in front their place,

00:55:41

great point because that has

00:55:45

been the case I can

00:55:46

say, and I spent time

00:55:48

on a hill and when

00:55:49

you're on the hell, you

00:55:49

think, you know, everything and

00:55:50

turns out, you don't know

00:55:51

anything. And then I went

00:55:52

to regulated industry at by

00:55:55

where I was to have

00:55:56

lobbyists at by when I

00:55:58

did get to meet with

00:55:59



a number of CEOs and

00:56:00

other leaders in the biotechnology

00:56:02

feel and just to underscore

00:56:03

the points that are being

00:56:05

made, nothing. I mean, the

00:56:09

lifeblood of our technology and

00:56:10

Life Sciences industry is intellectual

00:56:12

property. It's by far the

00:56:14

most important thing, it allows

00:56:15

you with strong Pattinson certain

00:56:17

pets to go out there

00:56:19

a tenth as well. FDA

00:56:21

granted the exclusivity. That's a

00:56:22



whole different things but you

00:56:23

know, that's another protection that

00:56:25

from FDA to not agree.

00:56:28

Edit the product, it generic

00:56:30

come product for certain. Of

00:56:32

time, but that's what allows

00:56:35

Life Sciences. Companies of all

00:56:38

sizes, go out and get

00:56:39

the capital that they need

00:56:40

to go down the path

00:56:42

of trying to commercialize the

00:56:45

product of the course of

00:56:46

10 15, 20 years and

00:56:48



these threats to Life Sciences.

00:56:50

Were they be the international

00:56:51

ones, Martis, mentions or, you

00:56:54

know, Mark and rights under

00:56:56

bidole act in the United

00:56:57

States, that abuse or threats,

00:57:00

which unfortunately come up every

00:57:05

now and then, which really

00:57:06

are of the greatest concerns

00:57:08

because the only way that

00:57:09

folks are going in the

00:57:10

best of billions of dollars

00:57:11

necessary to develop new Therapeutics

00:57:13



is with the assurance that

00:57:14

they can protect these from

00:57:16

competition for a. Of time.

00:57:18

And if you then have

00:57:19

whether the domestic US government

00:57:21

or international government saying that

00:57:23

during because his ex-wife That

00:57:29

really is chilling to investment

00:57:31

in life sciences. Well, I

00:57:33

like the the continued use

00:57:35

of Life blood since we

00:57:37

are talking about life sciences.

00:57:38

I mean, we did hear

00:57:39



a lot about the kind

00:57:40

of concerned about exclusivity. We

00:57:44

haven't even invoked Waxman but

00:57:47

we'll come back to that.

00:57:47

Perhaps two things just to

00:57:49

throw it on the table.

00:57:50

So that folks can pick

00:57:51

it up and talk about

00:57:52

it is we haven't really

00:57:53

spoken about generics in this

00:57:56

in this space and the

00:57:58

other thing we haven't really

00:57:58

chatted about is and I

00:58:01



know Marty can probably speak

00:58:02  
to this too. Is that

00:58:04  
the exclusivity periods? Or that

00:58:06  
kind of Ip protections and

00:58:07  
some of the multi-national big

00:58:10  
regulatory big treaties, right? So

00:58:12  
there was a lot of

00:58:13  
criticism back when the United

00:58:14  
States was a signatory of

00:58:17  
the TPP about the, the,

00:58:19  
the protection, that the United

00:58:21  
States helped broker in the

00:58:23  
IP space, and as one

00:58:25



of the leading Innovative markets

00:58:27

in the world, Probably a

00:58:29

lot of your clients. Brent,

00:58:30

we're not thrilled with with

00:58:31

what the United States provided

00:58:33

for, in that agreement. So

00:58:34

we can, we can talk

00:58:35

a little bit about that

00:58:36

to let me just shift

00:58:38

gears for a second and

00:58:40

talk about Trade Secrets and,

00:58:44

and go back to basics.

00:58:45

You are a lawyer to

00:58:47



go back to basics. And

00:58:50

those Basics are arbitration requires

00:58:53

Trivedi, right? And When someone

00:58:57

steals or is attempting to

00:58:59

steal your IP and there's

00:59:02

a trade secret issue, you

00:59:04

don't always have direct privity

00:59:06

with those with that person.

00:59:08

Like, I'm thinking about a

00:59:09

rogue employee or something else.

00:59:11

So how do we get

00:59:12

around those tricky? Little issues

00:59:14

in in the trade secrets

00:59:16



space. Anyone want to handle

00:59:18

that? These were not pre-planned

00:59:23

questions, if that's, if that's

00:59:24

too much of a stump

00:59:26

stumper, or it's improperly phrased

00:59:29

to let me know. Brent,

00:59:33

go first. There it is.

00:59:34

Haha. Okay, well that bought

00:59:37

enough time for the most

00:59:39

competent person on the panel

00:59:40

to answer it. In my

00:59:43

experience that hasn't actually really

00:59:46

been an issue in that

00:59:50



it's been kind of a

00:59:51

company to company. You know,

00:59:54

you stole our Trade Secrets

00:59:55

allegation. And even if it's

00:59:59

pinned on a date of

01:00:01

which specific, you know, actors

01:00:04

might have done. The, the

01:00:05

stealing really that the companies

01:00:09

are responsible for the actions

01:00:10

of their place. So it

01:00:11

hasn't actually, you know, manifest

01:00:14

itself. Now, what I could

01:00:15

see because of the interaction

01:00:18



between these International arbitration and

01:00:20

litigation is you could see

01:00:22

a situation where you know

01:00:24

company is just Company B,

01:00:26

you know, for because they're

01:00:30

Rogue employee, you know, torque

01:00:32

but the trade secrets of

01:00:33

company a and then left.

01:00:34

Start company C or something

01:00:36

like that. And Company B

01:00:38

is like a better Target.

01:00:39

You know, you could see

01:00:40

some then, parallel litigation where

01:00:42



Company B sues its former

01:00:44  
employee. So I could spin

01:00:47  
off into In two other

01:00:50  
kind of parallel litigation tracks.

01:00:54  
And I have seen, you

01:00:56  
know, situations where again going

01:00:59  
to the messiness of these

01:01:01  
carve-outs where, you know, if

01:01:04  
your have a trade secrets

01:01:05  
litigation. But it it's really

01:01:06  
kind of a patent dispute

01:01:08  
disguised as a trade secrets

01:01:09  
litigation, then, maybe one of

01:01:12



you could go to court

01:01:14

and get like a declaratory

01:01:15

judgment that you didn't infringe

01:01:16

the patent or something like

01:01:17

that, I would run in

01:01:18

parallel. So I think you

01:01:20

could have parallel litigation against

01:01:22

the Rogue employee. If that's

01:01:23

truly the case, I think

01:01:25

they then be knowledge. You

01:01:27

have to consult your patent

01:01:28

College. We have to consult

01:01:29

your employment law colleagues still.

01:01:32



Like, when you're responsible for

01:01:33

the Rogue employee, or whether

01:01:35

you're some kind of Defense,

01:01:35

I'm so I think it

01:01:37

could, it could play in

01:01:39

but I think it would

01:01:40

be litigated and contested issue

01:01:42

because in my experience is

01:01:44

the companies responsible for the

01:01:47

trade-secret theft in terms of

01:01:48

the allegations So but it

01:01:52

also, I guess the last

01:01:52

thing I would say is

01:01:53



if it is truly that

01:01:54

you know it may be

01:01:57

a dispute. That's resolved short

01:02:00

of completing the arbitration, the

01:02:03

parties, the best. You anticipated,

01:02:06

the exact fact that I've

01:02:08

litigated. I mean we had

01:02:09

a situation under a licensing

01:02:11

agreement that we allege there

01:02:13

was a patent infringement that

01:02:15

infringement case went forward in

01:02:17

the in the kind of

01:02:18

us courts. But in parallel

01:02:21



there was the possibility because

01:02:23

of the draft arbitration clause

01:02:24

in the licensing agreement to

01:02:25

bring a parallel arbitration on

01:02:27

different issues and it was

01:02:29

actually the threat of the

01:02:30

arbitration that resolves the overall

01:02:34

dispute because the Patton courts

01:02:36

were taking a while and

01:02:39

it's too high risk for

01:02:40

both parties to have a

01:02:42

disposition on on the patent.

01:02:45

At and the real issue

01:02:47



was the potential improper use

01:02:49

of of the, the product

01:02:51

under the licensing agreement, which

01:02:52

was resolved through the threat

01:02:54

of arbitration in an imminent

01:02:56

damage which was going to

01:02:57

go a lot quicker. So

01:02:58

arbitration is a tool in

01:03:01

the kind of, let's say,

01:03:04

more kind of prosaic litigation

01:03:07

strategy, that a lot of

01:03:09

our clients are going to

01:03:10

be interested in another. Another

01:03:12



question I had in this

01:03:14

one is I guess for

01:03:16

Peter and Marnie is she

01:03:21

mentioned ists or investment treaty

01:03:23

protections. What are the compulsory

01:03:26

licenses is certainly one of

01:03:27

them but what are the

01:03:28

other kinds of State actions

01:03:30

that could give rise to

01:03:31

a dispute in this space?

01:03:34

Just kind of throw some

01:03:35

of those out on the

01:03:36

table. Yeah, well in the

01:03:39



NAFTA, dispute between Lily and

01:03:42

Canada, it had to do

01:03:44

with the failure to provide

01:03:46

patent protection, in accordance with

01:03:49

International standards in the standards

01:03:51

that are in the the

01:03:52

treaty. It also can be

01:03:54

on the new regulatory side

01:03:57

where the country's regulatory approval

01:04:03

to generics for products that

01:04:06

are still protected by patents

01:04:08

and the interplay between the

01:04:10

IP protections and the Regulatory

01:04:14



and data exclusivity protections there.

01:04:18

And you know I can

01:04:21

as I said for me

01:04:23

and my experience some of

01:04:26

the investment treaty issues really

01:04:28

are when I pee kind

01:04:31

of bleeds over into industrial

01:04:32

policy. So you know, if

01:04:34

there is a domestic Champion

01:04:37

that a company Are there

01:04:39

a country or their regulatory

01:04:41

authorities are trying to help

01:04:43

particularly say? I know a

01:04:45



generic company that would like

01:04:47

to have access to some

01:04:48

of the IP information that

01:04:51

the government has a because

01:04:53

of the regulatory approval process.

01:04:55

Then there could be some

01:04:57

misuse of that intellectual property

01:05:01

that also could run afoul

01:05:02

of investment treaty protection. So

01:05:06

those are just some of

01:05:07

the issues that come to

01:05:10

mind, but you also I

01:05:11

know have arbitrator in this

01:05:13



area. So my father's other

01:05:15

thought, well, I just just

01:05:16

kind of 12 finger follow

01:05:17

up on that. Do you

01:05:19

see? Did you see governments

01:05:22

laying claim to too? Kind

01:05:25

of some of the defenses

01:05:27

that they might have with

01:05:28

regard to public policy essential

01:05:31

security card balance during pandemic

01:05:32

things like that playing more

01:05:33

ascendant role in in investment

01:05:36

disputes or do you mean

01:05:39



industrial industrial policy tool? Sounds

01:05:41

like a claimant's Prayers. If

01:05:45

you were representing the government,

01:05:47

you could say, well this

01:05:48

is a matter of public

01:05:49

policy and public health, and

01:05:50

therefore it's not covered under

01:05:51

the treaty. So I think

01:05:54

the public policy exception, I

01:05:55

mean that would be my

01:05:56

go to its public health

01:05:58

of its public policy and

01:06:00

that is a go-to for

01:06:01



many governments and I think

01:06:02

you know, it's going to

01:06:03

be it's an arbitrator's job

01:06:05

to try to sort through,

01:06:07

you know, what is a

01:06:09

legitimate public policy exception and

01:06:12

what is not. So I

01:06:14

think yes, like that's an

01:06:15

issue that we'll get litigated

01:06:17

in almost any life sciences

01:06:20

related, investment treaty to spew

01:06:23

in my view because it's,

01:06:24

that's available to say, like,

01:06:26



what we needed to do

01:06:26

this because it's in the

01:06:27

public interest. But I think

01:06:29

that that is really the,

01:06:30

the beginning of a conversation

01:06:33

and scrutiny by the arbitrators,

01:06:35

and not really an endpoint,

01:06:37

because there may have been

01:06:39

other ways to go about

01:06:40

it, you know, was it

01:06:42

done in a manner consistent

01:06:43

with Weather IP obligations and

01:06:46

international IP Norm. So I

01:06:48



think it it's kind of

01:06:50

it's a starting place but

01:06:51

not really the ending bending

01:06:52

place. That would be, that

01:06:54

would be my view and

01:06:55

National Security. We can all

01:06:59

probably have an opinion on

01:07:00

that, but in my mind

01:07:01

it's not a good fit

01:07:02

for this situation. I guess

01:07:05

I would just like Omar

01:07:06

knees, and same to you.

01:07:07

We have that. We had

01:07:08



a case where involving, a

01:07:09

taking of a distribution Network

01:07:11

and absolutely. The first offense

01:07:13

was public health, it's in

01:07:15

the, it's in the public

01:07:16

good. That may be an

01:07:18

easier argument to make, when

01:07:19

you're talking about a, you

01:07:21

know, media James here is

01:07:22

gene therapy center or the

01:07:24

side of us that we

01:07:25

have the clinical trial and

01:07:27

it was, it was a

01:07:30



bit more difficult than, in

01:07:31

that case that the arbitrator's

01:07:33

we're, we're fairly concerned about

01:07:35

the legitimacy of a public

01:07:37

policy. I mean, is it

01:07:41

public policy to try to

01:07:43

on Shore or Force Supply?

01:07:45

Chains back back on tour

01:07:47

in a there could be

01:07:48

damaged there to to those

01:07:49

folks who can do it

01:07:50

with better margins offshore and

01:07:53

now we're being forced it

01:07:54



to move forward. So let

01:07:57  
me, let me see. We

01:07:58  
have about 10-15 more minutes,

01:07:59  
folks in the audience had

01:08:02  
any questions. Don't be bashful.

01:08:05  
Yes, please. If you could

01:08:06  
just, we could get you

01:08:08  
a microphone. We have to

01:08:11  
use this one. Sorry. Thank

01:08:17  
you for this bike. So

01:08:19  
thank you. Thank you for

01:08:21  
this morning has been wonderfully

01:08:27  
or an introduction to that

01:08:29



topic. Forgive my ignorance, why?

01:08:32

What is the purpose of

01:08:33

carving out patent disputes in

01:08:36

the dispute. Resolution close. Peter

01:08:42

gave me the mic. Background

01:09:37

background. Mike's on, but they

01:09:43

can hear us at home

01:09:44

too, so that's good. Okay.

01:09:46

And I can protect so,

01:09:48

so so in my mind,

01:09:50

you know, that is one

01:09:52

of the issues, its predictability,

01:09:53

I'm its expertise. It's the

01:09:56



fact that you have relied

01:09:58

on your, for, your US

01:10:00

Patent. You know, you've relied

01:10:01

on a certain set of

01:10:03

us standards and it kind

01:10:06

of happened to your product

01:10:07

at its. Unless you, you've

01:10:10

decided you're going to have

01:10:11

like three pain experts, as

01:10:16

your arbitration panel who will

01:10:18

be applying US law. There's

01:10:19

some risk. There's also no

01:10:20

chance of appeal and to

01:10:22



use our favorite phrase, the

01:10:24

lifeblood of these companies is

01:10:26

IP. A lot of General,

01:10:29

counsel's are quite wary of

01:10:32

there. Being no appeal process

01:10:34

with regards to litigating a

01:10:37

patent. So that that's in

01:10:38

my experience. I'm sure. Observations

01:10:43

very consistent, even in the

01:10:44

US. If you just look

01:10:46

at litigation, there's a remarkable

01:10:48

amount of that at the

01:10:49

circuit court level of overruled

01:10:53



Ip decisions. And it's often

01:10:55

the case that when were

01:10:56

involved in a dispute from

01:10:58

the start, the parties know

01:11:00

that they're really positioning themselves

01:11:01

for a later trial because

01:11:03

in the first instance, they

01:11:04

have a judge who isn't

01:11:05

burst in the architecture of

01:11:06

Ip law and all the

01:11:08

intricacies of the IP issues.

01:11:09

And so they're really establishing

01:11:11

a record and I think

01:11:13



you see the same thing

01:11:13

in arbitration. It's really difficult

01:11:15

you know speak about finding

01:11:20

arbitrators to both have the

01:11:22

subject matter knowledge to arbitrate

01:11:24

these disputes are free of

01:11:27

any kind of encumbrances that

01:11:29

would make it inappropriate for

01:11:30

them to hear them. And

01:11:31

then you want them to

01:11:32

be IP experts on top.

01:11:33

That's that's a very, very

01:11:35

tall order and you might

01:11:37



be able to find three

01:11:37

people and they might be

01:11:38

able to schedule you in

01:11:39

a two and a half

01:11:40

years from now. You get

01:11:42

the tents to really be

01:11:45

a potential drag on on

01:11:47

the arbitration process. Not that

01:11:49

I think it's a walk

01:11:50

in the park trying to

01:11:50

run a parallel arbitration with

01:11:53

an with an IP carve

01:11:54

out some time in for

01:11:56



investment treaty arbitration. And also

01:11:57

want, probably those arbitrators to

01:11:59

have some familiarity with public

01:12:00

international law and how to

01:12:01

read a treaty. So later

01:12:03

that on top two of

01:12:04

you were looking to be

01:12:05

a unicorn in the space.

01:12:07

Now, you know what, you

01:12:08

need to get expert on

01:12:09

and then you'll get appointment.

01:12:10

Other other questions from the

01:12:12

audience. Set the mic on

01:12:17



the table. You might not

01:12:18  
hear it in the room

01:12:19  
but it is coming through

01:12:20  
at home. So if you

01:12:20  
can hear us, then we

01:12:21  
can use the mic on

01:12:22  
the table. Thank you very

01:12:25  
much for all the enlightenment

01:12:28  
that you have provided. I

01:12:29  
had a thought concerning what

01:12:34  
is becoming or has become

01:12:35  
a trend with respect to

01:12:37  
to trade at which is

01:12:40



trying everyone, perhaps let buy

01:12:42  
it by the us at

01:12:43  
some stage, but everyone is

01:12:44  
really trying to bring production

01:12:46  
on Shore and and somehow

01:12:50  
require National produce or or

01:12:55  
input sensor. And that made

01:12:56  
me think about the performance

01:12:58  
requirements that are in various

01:13:01  
free trade agreements. Mostly had

01:13:04  
those that by the us

01:13:05  
but in general in free

01:13:06  
trade agreements. We don't we

01:13:07



don't have performance requirements in

01:13:11

necessarily in the old model

01:13:14

bilateral. Entreaties. And, and, and

01:13:17

that made me think whether

01:13:18

or not for Life Sciences,

01:13:20

because be sure of whether

01:13:22

you going to produce on

01:13:24

Shore or elsewhere. In the

01:13:26

our time that Tetra comes

01:13:28

to mind whether the network

01:13:31

of investment treaties including fdsfds

01:13:34

generally do but but those

01:13:36

are not most of the

01:13:37



bilateral investment treaties, whether the

01:13:40

network network of investment treaties

01:13:42

is Israeli. ready or or

01:13:47

provides the tools to prevent.

01:13:53

Did the performance requirements that?

01:13:56

Why would she be in

01:13:57

in another, in in free

01:14:00

trade agreements and whether that

01:14:01

is a rather than issue

01:14:04

for Life Sciences. So any

01:14:07

any takers on that? I

01:14:09

do think that the majority

01:14:12

of markets where you have

01:14:16



let you know this question

01:14:19

posed, whether it be as

01:14:21

an Innovative Market or Market

01:14:23

are in some ways at

01:14:24

this point. Covered under one

01:14:26

of the larger ftas, as

01:14:28

the spaghetti Bowl goes and

01:14:30

the end of the clever

01:14:31

use of for greater certainty

01:14:33

retroactively, perhaps cover some of

01:14:37

the first and second-generation bits.

01:14:39

I'm not sure if that's

01:14:40

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

01:14:42



an absolutely good point. I,

01:14:44

I, I, I am not

01:14:46

aware of the 20 cases,

01:14:48

that, Peter mentioned that, that,

01:14:51

that question is, is But

01:14:54

I do think that one

01:14:55

of the interesting things will

01:14:56

be how robust some of

01:14:57

those FDA is that that

01:14:59

include some of these Innovative

01:15:01

Concepts retroactively work backwards to

01:15:05

handle, some of the less

01:15:07

robust B. But I mean

01:15:09



this this goes to a

01:15:10

larger discussion about whether 1st

01:15:13

and 2nd generation, bilateral investment,

01:15:14

treaties are going to survive

01:15:15

over the next 10 years.

01:15:16

Might my own suggestion is

01:15:18

that it will be very

01:15:19

difficult for them to persist,

01:15:20

but that's just my view

01:15:21

Barney. take, take take this

01:15:25

one with some Okay, we've

01:15:30

got the better microphone now,

01:15:31

I agree. It's a very

01:15:34



good question. I mean, I

01:15:35

think gone older B. It

01:15:37

really might depend on how

01:15:38

it's implemented because you could

01:15:40

see it be implemented in

01:15:42

a way that could give

01:15:43

rise to some kind of

01:15:45

national treatment around my phone

01:15:46

claim or maybe it's implemented.

01:15:49

Like, in a very kind

01:15:50

of arbitrary way. So in

01:15:52

my mind and maybe also

01:15:54

for older generation B, I

01:15:56



think there's a question. Is

01:15:57

there a Gap? Or maybe

01:16:00

depending on how it's implemented?

01:16:02

You could still do something,

01:16:04

but I do think that

01:16:06

To your point. I mean

01:16:08

right now this idea like

01:16:10

onshoring as part of an

01:16:12

industrial policy after it is

01:16:13

something that everyone's doing and

01:16:15

I don't think I got

01:16:16

another face of it. That

01:16:17

itself would be a treaty

01:16:19



violation. But I do think

01:16:20

to your point like, well

01:16:22

how you do it, you

01:16:24

need to be thinking about

01:16:25

these International obligations, and I'm

01:16:28

sure Brent can a test

01:16:30

from a Time on the

01:16:31

hill, whenever our Congress is,

01:16:33

considering are these types of

01:16:35

Provisions are. There's usually plenty

01:16:37

of people up there kind

01:16:39

of whispering in the ears

01:16:39

of folk saying, you know,

01:16:41



hey, the US has a

01:16:42

lot of international agreements topic

01:16:44

that you probably should consider

01:16:46

as your drafting or legislation.

01:16:47

So, I imagine there's a

01:16:49

way to do it. That's

01:16:50

consistent with those obligations, but

01:16:53

there's probably also wasted you

01:16:54

at that would be inconsistent.

01:16:55

And bring can tell us

01:16:57

how, how well-received there that

01:16:59

the statement to Congress, there

01:17:01

are a lot of International

01:17:02



Airport received that phrases. Oh

01:17:07

yeah, there was like oh

01:17:07

okay well then we won't

01:17:08

touch it as well. Any

01:17:13

other questions from the audience?

01:17:16

Does a question online? Excellent.

01:17:19

Jose Antonio, would you like

01:17:21

to to to be our

01:17:23

online? The face of the

01:17:25

online community. Show the questions

01:17:37

from Laura Richardson, and it's

01:17:40

to Peter. So, there you

01:17:42

go. Given the difficulties and

01:17:44



inherent speculation required in quantifying

01:17:47

Damages in life sciences. Dispute,

01:17:49

has there been any consideration

01:17:52

or attempt to include liquidated?

01:17:55

Damages Clauses in life sciences,

01:17:57

commercial collaboration agreements for breaches

01:18:00

of certain terms and parentheses

01:18:02

such as are common in

01:18:05

construction agreement, or there's a

01:18:08

second question or are their

01:18:11

unique features in the Life

01:18:13

Sciences field, that wouldn't would

01:18:15

not lend itself to liquidated

01:18:17



damages causes That's an excellent

01:18:21

question. Well well, he's getting

01:18:23

a microphone. I'm sure French

01:18:24

are well-versed in liquidated. Damages

01:18:26

Clause is speaking of kind

01:18:28

of cross, cultural conflict, between

01:18:29

innovators in other jurisdictions. Now

01:18:31

that you have found that

01:18:32

was why I can't speak

01:18:35

to the universe but only

01:18:37

infrequently come across attempts to

01:18:39

introduce the concept of liquidated

01:18:41

damages within a life sciences

01:18:43



contact. I think the challenges

01:18:45

are typically that if you

01:18:48

takes a trade secret misappropriation,

01:18:50

where are you? You for

01:18:53

some of your .45 protocols

01:18:55

or are they may be

01:18:57

at being expropriated, they're still

01:19:00

value and the company doesn't

01:19:02

want liquid ant baits. What

01:19:04

they want is to continue

01:19:05

the development of their products

01:19:06

and usually 2 to block

01:19:10

the party. This Miss appropriate

01:19:12



the assets in. So it's

01:19:15

often the case that we

01:19:16

find ourselves in a little

01:19:17

bit of a difficult situation

01:19:18

where we are To assess

01:19:21

damages with the hope that

01:19:22

it's irrelevant because the real

01:19:24

goal of their arbitration is

01:19:26

to secure the IP to

01:19:28

secure the path forward and

01:19:29

to ensure that the kind

01:19:33

of ancillary roads to investment

01:19:35

remain open. And I think,

01:19:36



maybe maybe that's the key.

01:19:38

Is that, you know, those

01:19:39

in life sciences, know that

01:19:41

the product that comes to

01:19:42

Market sometimes Bears, a resemblance

01:19:44

to what you thought you'd

01:19:46

bring 20 years ago. But

01:19:47

often the case, it's that

01:19:50

along the path. You found

01:19:53

other opportunities, other therapeutic categories,

01:19:55

other aspects of the product

01:19:58

to be developed so that

01:19:59

you have a therapy that

01:20:00



still valuable to patients, still

01:20:03

commercially viable, but not exactly

01:20:05

where you thought you'd end

01:20:06

up. And, and the question

01:20:08

of whether the promised utility

01:20:10

is, is needs to be

01:20:12

specified, has been litigated in

01:20:14

in our space right now.

01:20:15

I would just add that

01:20:17

to Peter's point. I have

01:20:19

clients who start Down who

01:20:22

acquired assets which are decades-old

01:20:26

protections for the indication and

01:20:30



the like, but like I

01:20:31

could think of on which

01:20:32

was a weight loss drug,

01:20:33

which ultimately was brought to

01:20:34

the market for Pediatric epilepsy.

01:20:37

You just never know where

01:20:39

the science is going to

01:20:40

lead you with products. We

01:20:44

have time for one more

01:20:45

question, don't be, don't be

01:20:47

shy. Anything else online? One

01:20:52

more question. It's David Engel

01:21:00

from a delivery. Thank you

01:21:01



for the panel, just a

01:21:02

question on potential threats to

01:21:04

to Life Sciences. It seems

01:21:07

to make more this requires

01:21:09

billions of dollars to invest

01:21:10

it in the night and

01:21:11

I did it extremely likely

01:21:13

to fail. I'm I'm actually

01:21:15

it's much easier to to

01:21:16

get financing to commit financing.

01:21:18

This idea when your monetary

01:21:20

environment, where is 11 Crest

01:21:23

Drive? Liquidity. Sloshing around in

01:21:25



also with your interest rate

01:21:27

environment, flat is the present

01:21:29

value of potential profits in

01:21:31

twenty years time as we

01:21:33

have to move out of

01:21:34

that era. When money is

01:21:35

little more expensive and we

01:21:37

didn't get those advantages, is

01:21:39

that a huge threat. I'll

01:21:40

be going to see a

01:21:41

reduction in innovation in the

01:21:43

future. I don't say so,

01:21:46

Is that a possibility that

01:21:47



they'll be far more disputes?

01:21:48

And typically we think when

01:21:49

it's less money sloshing around,

01:21:51

people, get paid for their

01:21:52

respects to get paid, something

01:21:54

you get dispute. So is

01:21:55

that a threat? Would I

01:21:56

have to cut everybody off

01:21:57

but I'm asking about 20,

01:21:59

no. We start with some

01:22:01

litigations and let me just

01:22:07

start with, thank you. It's

01:22:10

not, it's not going to

01:22:12



be good for the US

01:22:13

government for the research and

01:22:17

development into new therapies vaccines

01:22:20

and the like by implementing

01:22:23

on the number to Rexburg

01:22:26

e r. A first a

01:22:28

price setting of a of

01:22:30

a maximum fair price for

01:22:33

a product. And then a

01:22:34

negotiation downward on that price

01:22:37

which is going to be

01:22:39

which is what is mandated

01:22:41

by the inflation reduction act

01:22:43



that the pharmaceutical industry to

01:22:45

biotechnology industry were very concerned

01:22:48

very opposed to the notion

01:22:51

that the government can be

01:22:52

directly negotiating on a subset

01:22:54

of very important Therapeutics and

01:22:55

they contend and I agree

01:22:57

with them that this is

01:22:58

going to be too, unfortunately,

01:23:00

less. Development. I've already seen

01:23:02

one company indicate that they're

01:23:04

not pursuing an indication which

01:23:06

they, otherwise would because they

01:23:08



did not want to potentially

01:23:10

in the number of years,

01:23:11

be subject to direct negotiation

01:23:13

with new play. Some reduction

01:23:14

act calls for so that

01:23:16

is of of great concern

01:23:19

to a life sciences community.

01:23:21

I absolutely agree with French,

01:23:24

in the, in, in the

01:23:25

short-term, Mark conditions, change economic

01:23:28

conditions, change investment in life,

01:23:30

sciences remains relatively stable, in

01:23:33

light of your economic factors.

01:23:35



What what really kills investment

01:23:37

is significant outside action, anything

01:23:40

that that chills the investment

01:23:42

opportunity or or you know

01:23:44

people who invest in life

01:23:45

sciences know they're playing a

01:23:46

long game. What they're concerned

01:23:48

about is the time consistency

01:23:50

problem of some significant change

01:23:52

while they're kind of waiting

01:23:53

for the fruits of that

01:23:54

investment. All that said it

01:23:57

is certainly true. Your second

01:23:58



question it is always the

01:24:00

case that we see an

01:24:01

uptick in disputes when economic

01:24:03

conditions get tight you know

01:24:06

back in 2018 and it's

01:24:09

hard to remember that. There

01:24:10

was a downturn economically before

01:24:12

the pandemic, which kind of

01:24:13

stole the headlines but they

01:24:15

said that was the most

01:24:15

recent example, we saw where

01:24:17

the economy tightened up and

01:24:19

suddenly partners with whom you

01:24:20



were, you were quite High.

01:24:21

The forge ahead with now

01:24:24

you're looking at a stance

01:24:25

and and we see an

01:24:29

uptick in arbitration, we see

01:24:31

an uptick in patent disputes

01:24:33

and we see a large.

01:24:34

I'll take you in competition

01:24:36

claim where everybody's looking for,

01:24:39

you know, some other Revenue

01:24:42

stream or a way to

01:24:44

reduce kind of an ongoing

01:24:46

cost line. Well, we are

01:24:54



at time at, so let

01:24:56

me Falls to me to

01:24:58

say, firstly, my lifeblood is

01:25:00

coffee and lunch and that

01:25:01

will be served outside to

01:25:02

directly after this panel. But

01:25:04

secondly, to thank this incredible

01:25:07

panel, providing very in-depth insights

01:25:11

into life sciences and how

01:25:12

they make late to the

01:25:13

arbitration and thank you to

01:25:14

you our audience at home

01:25:16

and here for your patience.

01:25:18



And of course again to

01:25:19

Jose Antonio, for inviting us.

01:25:21

Also, thank you very much.