MINTZ

United States Patent and Trademark Office and the Department of Justice

Promoting Innovation in the Life Science Sector and Supporting Pro-Competitive Collaborations: The Role of Intellectual Property

September 23 – 24, 2020

The program sought to identify and clarify the ways in which the patent system has been leveraged to address the ongoing COVID-19 crisis. Co-Hosted by the USPTO and DOJ, the program featured industry executives from both large and small entities, private practice attorneys, and officials from both agencies, including Andrei Iancu, the Under Secretary of Commerce for Intellectual Property and the Director of the USPTO, and Makan Delrahim, the Assistant Attorney General of the DOJ's Antitrust Division.

The Mintz team attended the event and we are pleased to provide this overview document.

A few thoughts in summary from our team:

- Speakers highlighted the important impact the life sciences industry has had on life expectancy and other health markers, and of the importance of limiting barriers while maintaining a system that rewards innovation.
- The USPTO continues to provide guidance to create an integrated approach to patent subject eligibility following decisions in important cases (Alice, AMP and Mayo, in particular). The 2019 Revised Patent Subject Matter Eligibility Guidance is the most recent from the USPTO.
- Varying industry perspectives were presented on the strength and value of the current patent system for protecting innovation and providing access to such innovation as a platform for technological advances. (see pages 5 – 6 for "Are Changes to U.S. Patent Law Needed to Better Support Innovation in Life Sciences and the Development of COVID-19 Solutions?")
- Director Andrei Iancu of the USPTO shared that preserving IP rights during a time of crisis, such as the COVID-19 pandemic, is critical. The speed with which the industry has responded is enabled by prior technologies, innovators of which were rewarded at the time for the lengthy efforts to achieve those successes. Our system encourages inventors now and will during future crises.
- Assistant A.G. Makan Delrahim of the DOJ shared that IP and antitrust complement each other and that his prior experience in the life sciences and with IP are valuable assets in his current role. He is a believer in balance between protecting innovation and maintaining an open market.
- See page 12 for an interesting discussion on "Competition and Collaboration: Examining Competitive Effects and Antitrust Risks Associated with Collaborations" which features insights from small biotechs, large pharma, academic research and the DOJ.

Day One

Opening Remarks

Opening remarks were delivered by USPTO Director Andrei Iancu. Director Iancu spoke about the role that the patent process plays in accelerating innovation in the life science sector. Iancu asserted that innovations in the life sciences have been able to alleviate suffering in the human condition and improve the quality of life, noting that life expectancy has doubled since the industrial revolution due to technological and medical advancements. One example of such an advancement is in the treatment of diabetes. Initially, diabetes was treated with a starvation diet and had a life expectancy of just two years following diagnosis. However, insulin was discovered in 1922, changing the course of diabetes treatment. According to Iancu, the patent system spurs innovation by disclosing new technologies for individuals to build upon and minimizing trade secrets. Additionally, the patent system makes intellectual property a legal and financial mechanism which protects innovators and allows them to capitalize off of their work. In light of the ongoing pandemic, the USPTO has implemented a variety of platforms to expedite the patent process and optimize existing resources. The foremost of these new platforms being the Patents for Partnerships programs. This program was an opt-in system for current patent holders to connect with potential licensees of their technologies in order to use existing infrastructure for new developments to address the pandemic. This program has been extremely successful and currently involved over 900 patent holders. Additionally, the USPTO had extended application deadlines and waived fees for COVID-19 related patents and has begun to disclose these technologies on the USPTO website earlier.

Session I: The Role of Patents in Research and Development of Therapeutics, Diagnostics, and Vaccines, Particularly During Pandemics

In this session, the link between patents and innovation, and the value of innovation in the diagnostic and therapeutic arena in improving public health was explored.

Presenter: ***Genia Long***, *Senior Advisor, Analysis Group*

In this segment, Long discusses the key role of patents in medical research and development. She began by framing technological innovation as a key determinant of economic and health progress. She specifically cited research in the prognosis of heart disease, stroke, various cancers hepatitis c, and HIV. The aforementioned ailments used to be somewhat fatal however due to economic developments in medical research and development, treatments have been discovered that have significantly increased life expectancy. For example, between 1990 and 2016, there has been a 2.1 year life expectancy improvement for individuals who have suffered a heart attack or stroke due to the creation of new pharmaceuticals.

Long further asserted that the key driver of such advancements is financial investment in medical and life sciences research. The research and development process for medical inventions is very protracted and costly. Additionally, the research forays are not always fruitful and therefore researchers don't recoup financial losses, which is why it is critical to receive external funding. Long contended that there is robust evidence that innovation responds well to economic incentives and that the rate for technological change is expedited when financial investment is present. She referenced the fact that new therapeutic and pharmaceutical development was significantly lower for cancers with less financial resources.

Next, Long pivoted to addressing the way that patents influence research and development for pharmaceuticals. The primary importance of patents is that the process of developing, approving and commercializing a drug is very expensive and without gaining proprietary technology, which is a financial mechanism as Director Iancu mentioned, the long term investment might not be worth it. Additionally, as part of the patent process, patent recipients receive a term of market exclusivity for their product which enables them to temporarily determine pricing in the market and create returns on their investment.

Despite the ostensible financial security that comes with market exclusivity, it has become clearer in recent years that this is a much more short term benefit than intended. The life term of some level of market exclusivity for a patent may be 20 years but the caveat to that is that the Food and Drug Administration (FDA) approval process for that biologic or pharmaceutical takes up a large portion of that term. FDA approval sometimes takes as long as 15 years. Therefore, the term of actual market exclusivity is significantly reduced.

Session II: Update on USPTO Guidance on Patentability of Life Sciences Innovations

In this session, the history of and the agency's most recent guidance to examiners on the analysis of claims for compliance with subject matter eligibility and disclosure requirements under the patent law was explained.

Presenter: ***Ali R. Salimi****, Senior Legal Advisor, Office of Patent Legal Administration, USPTO*

Salimi primarily focused on the variety of legal guidance available for patent seekers and the different criteria which exists to determine patent eligibility. There are four types of patent eligible subject matter: processes, machines, composition of matter and manufacturing components. The Supreme Court has held abstract ideas, laws of nature/natural principles, and natural phenomena are not eligible for patents under 35 U.S.C.S. § 101.[1] Prior to 2012, there was not much succinct guidance on the eligibility of life sciences related patents but there has been some progress in the past decade. There have been a few significant Supreme Court cases that have further shaped judicial review of patented materials. The first of these being *Mayo v. Prometheus*[2] in 2012. In this case, there was a unanimous decision that there would be a two-part eligibility test for patent claims focused on laws of nature. Following this, in 2013's *AMP v. Myriad Genetics*[3]*,* the court held that claimed products must be markedly different than what occurs in nature in order to be eligible. In 2014, in *Alice Corp v. CLS Bank*[4]*,* the court expounded upon the two-part eligibility test which was created in the *Mayo* proceedings. The court declared that the two-part test applied to all products and processes claims that were previously subject to any judicial exception (laws of nature, abstract ideas, and natural phenomena). Here, the two-part test became a much more procedural analysis with defined parameters. In part one, it would be determined if the claim was

[1] https://www.uspto.gov/sites/default/files/101_step1_refresher.pdf

[2] https://www.supremecourt.gov/opinions/11pdf/10-1150.pdf

[3] https://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf

[4] https://www.supremecourt.gov/opinions/13pdf/13-298_7lh8.pdf

directed to a judicial exception and if so, in part two, the claim as a whole would be analyzed to determine if the claim amounts to significantly more than the judicial exemption itself.

In accordance with these precedents, the USPTO has issued multiple interim guidance documents since 2014. The purpose of these documents is to create an integrated approach to eligibility claims, explain the USPTO's interpretation of subject matter eligibility requirements as it relates to *Alice Corp, AMP,* and *Mayo,* reflect significant changes from previous guidance, and include discussion of case law precedent with examples illustrating application of eligibility analysis to various types of claims. The most recent and updated version of USPTO guidance is the 2019 Revised Patent Subject Matter Eligibility Guidance. At the culmination of his presentation, Salimi was asked about the impact of the 2019 guidance in relation to rejections or patent losses in court to which he responded that the stakeholders have praised the guidance and said it has helped to mitigate legal challenges.

Session III: Life Science Patents in Practice

In this session, speakers shared their experience with ways that the patent system protects inventions in the life sciences, promotes innovation and facilitates collaboration in life sciences.

Presenters: ***David E. Korn****, Vice President, Intellectual Property and Law, Pharmaceutical Research and Manufacturers of America (PhRMA)*

Dr. Gaby Longworth*, Director, Sterne Kessler Goldstein and Fox, LLP.*

During this session, Korn primarily built upon earlier points regarding the lengthy process that is research and development for new pharmaceuticals. He agreed that patents and the protection that they provide enable biopharma companies to invest in the lengthy, costly, and uncertain research and development process for new drugs. In order to further clarify just how lengthy the process is, Korn described in detail the discrete steps biopharma companies must take before a new drug can enter the market. First, there is the general research and discovery of a new drug or compound. Following this there are clinical trials performed on animals. If these trials are successful, then the company must submit an Investigative New Drug Application to the FDA before they are able to begin testing on humans. Clinical trials with human subjects go through a multitude of phases which take years to complete. If the outcome of clinical trials with human subjects is positive then a company may submit a New Drug Application to the FDA for final approval before that substance can be introduced to the market. At each of these stages many compounds fail. In fact, fewer than 12% of medicines make it through the FDA approval process.

Dr. Longsworth focused both on the legal definitions of certain patent types and on the methods of use aspect of patented pharmaceuticals. Dr. Longsworth also reemphasized the power of patents in that they encourage the disclosure of the workings of inventions to the public, encourage investment by providing a barrier to entry for those who would copy an innovation, prevent others from using inventions as a trade secret and recoup money spent on research and development. She then discussed the pharmaceutical or small molecule drug approaches to patents. The first of them being the New Drug Application ((501(b) (1)) which is reserved for new molecular compounds, new formulations of a previously approved drug, new combination of two or more drugs, or new indication for an already marketed drug. The ((501(b)(2)) or "paper" NDA, which is a modification of an approved drug and most often manifests in the form of generics; and the 505(j) or the "abbreviated" NDA is for a duplicate of a previously approved drug and must have the same dosage and method of use of its predecessor. Dr. Longsworth noted

that the goal for many companies is to have as many patents for as many variations of a compound as possible in order to maximize its licensing capacity and because derivative patents move through the patent office fairly quickly as opposed to patents for new compounds.

Panel Discussion 1: Are Changes to U.S. Patent Law Needed to Better Support Innovation in Life Sciences and the Development of COVID-19 Solutions?

Using the COVID pandemic to exemplify and emphasize the importance of innovation, the panelists exchanged ideas about whether changes are needed to support innovation in the life sciences sector and to support collaboration.

Moderated by: USPTO Director Andrei Iancu

Panelists:

***The Honorable Paul R. Michel**, Chief Judge, U.S. Court of Appeals for the Federal Circuit (Ret.)*

***Steven Caltrider**, Vice President of the General Patent Counsel, Eli Lilly and Co.*

***Karin Hessler**, Assistant General Counsel, Association for Accessible Medicines (AAM)*

***Arti Rai**, Elvin R. Latty Professor of Law and Co-Director of the Center of the Center for Innovation Policy, Duke School of Law,*

***Corey Salsberg**, Vice President and Global Head of IP Affairs, Novartis*

***Hans Sauer**, Deputy General Counsel and Vice President for Intellectual Property, Biotechnology Innovation Organization*

***Hiba Zarour**, Head of IP Department- Global Division, Hikma Pharmaceuticals*

Judge Michel kick started the discussion by offering criticism of the judicial review process for patents. He stated that patent law is very unpredictable in terms of eligibility which deters business leaders and venture capitalists from investing, therefore changes to the law and the way it is being interpreted are needed. Judge Michel found the guidelines to be too vague and that the courts were using very broad strokes in their interpretations. One primary flaw is the use of case law for eligibility. Michel conceded that he oftentimes didn't totally understand the way precedent applied despite having overseen dozens of patent cases. Each individual case is unique and therefore using catch all precedents can do more harm than good. He mentioned that many judges and other legal professionals have begun to use an "I know it when I see it" mantra when applying eligibility tests which creates large differences in the outcomes of similar cases because there is no objectivity. He further criticized the language in Section 101 for its ambiguity, particularly undefined terms such as "significantly more" and "abstract ideas." Due to the vagueness of the guidance, there is not a rigid or methodical structure to analysis of eligibility and courts are not interpreting the law consistently.

Salsberg pivoted from Michel's points to instead compliment the many benefits of the current patent system especially in light of the coronavirus. He stressed that patents have given researchers libraries of millions of novel compounds and existing technologies which could be repurposed in order to tackle the virus. He credits this existing infrastructure for being the catalyst

for 1500 active clinical trials of treatments, 35 vaccine trials and 140 vaccines in preclinical studies all to address coronavirus. At this time, Director Iancu asked Salsberg to respond to criticism that building on existing technology for new developments inappropriately extended the life of a patent term. Salsberg responded that patents are only covered for one use so new patents for new uses would begin a new term, not affecting the previous one. Additionally, patent terms are supposed to be 20 years per invention, but in reality most patents only use 11-13 years of that term if the drug creation process is extremely expedited. Further, it takes approximately 10-15 years to develop a drug and get it on the market therefore a company would never recoup their net losses if they only used the original term for one patent which is why it is important to patent several competencies of a compound.

Zarour was asked to address Salsberg's statements from the perspective of a company that specializes in generics and to comment on whether the current patent system strikes the appropriate balance between supporting innovation and providing access to multiple players. Zarour affirmed that the current system does strike the appropriate balance but did point out some anticompetitive loopholes. The foremost of these loopholes being patents pools which Zarour stated were a major impediment on new insulin therapeutics being developed and the price gouging of insulin products.

Karin Hessler found it to be important to strike a balance between protecting innovation and companies monopolizing the patent process. For example, some companies will have hundreds of patents for every derivative of a compound and charge a hefty fee for others to license that compound and repurpose it. This prevents other players from building upon existing patents. She also pointed out that it is becoming increasingly difficult for patent challenges to be settled in court due to ambiguity in the law. She specifically pointed to the way in which some states attempted to regulate patent disputes through various statutes which hinder companies from settling ahead of court proceedings but rather almost forcing companies to litigate the matter. Hessler claimed this is particularly harmful for life sciences companies because many disputes are for generics and the settlement process can expedite generic access by up to 10 years. Eliminating it as an option limits access for patients who need alternatives to be available on the market.

Sauer addressed how IP can accelerate innovation. He first started out by saying that the ongoing pandemic has created more public discourse about IP and the patent process, being that it is the first time that the general public collectively had to wait for a drug. People are beginning to see the crucial role that IP plays in our lives. Sauer stated that at all times, but especially in light of COVID-19, collaboration is essential in accelerating innovation to meet the needs of the people. Most biotech companies are smaller with limited resources but they hold approximately 70% of the research and development pipeline at any given time. Smaller biotech companies expect to pass their technologies onto a larger company with better capacities to see a product through getting on the market. For example, a company with the capacity to develop a drug might not be able to conduct a clinical trial and a company that is able to conduct a clinical trial might not be able to manufacture in larger numbers or create a global supply chain. For this reason, it is of the utmost importance for companies to collaborate with one another and combine efficiencies to allow products to reach the market sooner. This has been the case for companies looking to solve the pandemic. 90% of current compounds in clinical trials are collaborations or licenses of repurposed drugs. Director Iancu asked Sauer if this surge in collaboration is due to the patent process or just the rush to capitalize off of COVID-19. Sauer found there was no evidence to support the latter. Of course, the incentive to patent coronavirus therapeutics is clear but it would not be possible to even leverage partnerships and existing technologies without the patent system.

Caltrider applauded the USPTO for being instrumental in supporting innovators specifically through the Patents for Partnerships initiative. He stated that he was much more open to patent pools especially to address unmet medical needs but was hesitant because most drugs have a variety of uses and the first use is not necessarily the best use. Caltrider wanted to avoid discouraging further innovation for a compound due to patent pools.

Rai agreed with Salsberg that the back stock of patents and the public exchange of knowledge is critical for innovation, especially in the face of a global health crisis such as coronavirus. She did find issues with the guidance in accordance with Judge Michel's remarks. She also pointed out that the guidance is even slimmer for biologics causing very few to be available on the market.

Session IV/Panel II: Copyright and Innovation in the Life Sciences

In this session, panelists explored copyright's integral role in supporting the dissemination of information and facilitating different licensing models. They also provided an overview of how copyright can encourage innovation in the life sciences.

Moderator: ***Susan Allen,*** *Attorney Advisor, OPIA, USPTO*

Panelists:

Bhamati Viswanathan*, Affiliate Professor, Emerson College*

Michael W. Carroll*, Professor of Law and Faculty Director, Program on Information Justice and Intellectual Property, American University Washington College of Law*

Mark Seeley*, Consultant, SciPub Law LLC and Adjunct Faculty, Suffolk University Law School*

Viswanathan began the session by clarifying the role of copyrights and distinguishing them from patents. Copyrights are a form of legal protection that provides authorship to an individual for the creation of books, music, software, databases, etc. Copyright protections are fixed and only apply to one work product and is a bundle of exclusive rights so products can be licensed. Dissimilarly to patents, there is no publication burden for copyrights. They are distributed through the U.S. Copyright Office, have global protections, are much less costly to secure and are infrequently denied. Copyrights also have a longer lifespan than patents and last for the copyright holder's entire life plus 7 years posthumously. Similarly to patents, there is a concern about striking a balance between ownership and access because you want to preserve authorship but still provide access to copyrighted material for others to build upon.

Carroll further elucidated the extent to which the digital age has influenced the way people perceive copyright issues. The internet has created an expectation of open access which for many people may mean free but that is incorrect. Open solely means being able to access content easily, therefore there needs to be a way for individuals to access content and repurpose it with proper attribution. However, it is impossible for some legal scholars to ignore the aspect of cost in the creation of an open access framework for a few key reasons. One, there are under resourced scholars who may be barred from content due to costs. Additionally when things are free someone may stumble upon something serendipitously and be inspired to innovate. Lastly, science is becoming increasingly interdisciplinary and researchers need access to a variety of content in order to make advancements. Cost can be prohibitive and discourage an interdisciplinary approach. The Office of Science and Technology Policy issued a memo which

directed all federal agencies to create public access policies which give people the opportunity to read, download, and analyze peer reviewed documents. Two separate camps have been created in response to this memo, one which calls for immediate open access -- making materials available online as soon as they are published, also known as gold open access. The other option is known as green open access which is the delayed digital publication of materials. Seeley found it useful to have a synthesis of the two to ensure that authorship is protected but access is not an obstacle.

Seeley spoke about the role of scientific journals in innovation. Scientific journals include contemporary research which is often copyrighted material. These journals provide a wide variety of research and access to copyrighted materials in singular volumes. This can encourage collaboration amongst unlikely collaborators or enable a research to find information they might not have access to otherwise. Though subscription based financing models for scientific journals may limit access to a certain degree, Seeley contended that journals in and of themselves expand access.

Day Two

Opening Remarks

Assistant Attorney General of the Antitrust Division of the United States Department of Justice, Makan Delrahim delivered opening remarks on day two. Delrahim began by stating that the second day of the webinar would have a much larger antitrust focus. With that being said, Delrahim reemphasized the way in which the ongoing pandemic has highlighted the importance of innovation in the life sciences, particularly in the realm of disease control and prevention. In this endeavor, intellectual property rights are critical because they encourage risk taking by offering some protection in a financially risky endeavor. Patent rights are explicitly mentioned in the U.S. Constitution because they are a method to incentivize human advancement. Innovation is related to antitrust because the creation of new products diversifies the markets and increases competition. Additionally, collaboration encourages efficiency. The DOJ's antitrust division recently released a report analyzing collaboration between companies that want to share information regarding their ability to manufacture antibody treatments for COVID-19 so that they may integrate in order to get treatments on the market faster. This underscores the way that companies can work together to meet shared goals.

Fireside Chat:

Moderated by: ***The Honorable Kathleen O'Malley,*** *Circuit Judge, U.S. Court of Appeals for the Federal Circuit*

Speakers: ***Andrei Iancu*** *and* ***Makan Delrahim***

Q: What is the USPTO doing to encourage innovation?

According to Director Iancu, patents inherently play a procompetitive role by incentivizing innovation, disclosing innovations, and creating a financial benefit to intellectual forays. Patents are especially important for small companies who may not possess sizable market power or

influence wherein a patent enables them to have a sort of power in their industry by having proprietary technology. To support this, the USPTO provides discounts to small business applicants and counseling for them as they navigate the patent process. In order to support innovation during the pandemic, the USPTO has promised to resolve patent applications within 6 months as well as the implementation of the Patents for Partnership program.

Q: What resources exist at the Justice Department to help small businesses navigate the patent system and the antitrust system?

Assistant A.G. Delrahim shared that the antitrust division often files amicus briefs and statements of issue to clarify matters regarding intellectual property and to make existing guidelines more clear. Under Delrahim's leadership, the department has written a significantly higher number of amicus briefs. In his view, improper implementation of the law impacts the way that the DOJ is able to enforce the law as they are bound by precedent. Therefore, it is useful to provide guidance on the front end. This action has been warmly received by judges who needed assistance understanding complex issues. For small businesses, there is the business review letter process. When businesses want to engage in any collaborative activity they can write the DOJ a letter requesting an evaluation of their actions to ensure they are compliant.

Q: Director Iancu, what is the primary message you want to convey when you participate in events such as this?

Director Iancu affirmed his belief that innovation is the main driver of economic growth and human development. It is critical to our lives and our economy and he intends to remind people of this. In his view, we have a duty to invest in innovators and direct our attention to development. Secondarily, intellectual property is the backbone of the innovation ecosystem. IP rights facilitate innovation especially in respect to international competition by providing protection and a return on the investment. Lastly, Iancu wants to galvanize individuals to become creators and innovators.

Q: Some people believe IP rights should be disregarded during COVID-19 in order to expedite the therapeutic development process, why is it important to preserve them during the crisis?

Director Iancu stated that it is even more important to preserve IP rights during a time of crisis because the only reason we have been able to see such significant research and development in a short period of time is due to preexisting technologies. Development in the life sciences space is particularly expensive and time consuming. The absence of IP rights means that there is no incentive to undertake these tedious but necessary projects. If we disregard these protections now, it is likely that there won't be anything to encourage inventors in the next crisis or pandemic.

Q: Assistant A.G. Delrahim, how has your background in life sciences and IP helped color your vision for the Antitrust Division?

Delrahim shared that IP and antitrust are great complements to each other. His experience with life sciences in his younger life enables him to see their close relationship clearly. It is essential to protect the inventions of innovators but also to maintain an open market. The life sciences sector is integral in our lives and the work of scientists and the National Institute Health leads to life saving treatments and we must have IP rights which allow for such scientific developments.

Session V: Collaboration and Licensing Strategies

In this session, participants discussed partnerships that facilitate the development of therapeutics and vaccines from research through the market-ready stage. Panelists considered public-private partnerships; private partnerships; exclusive versus non-exclusive licensing; ownership rights; and information pooling.

Moderator: ***Brian Pandya,*** *Deputy Associate Attorney General, U.S. Dept. of Justice*

Presenters:

Laura A. Coruzzi, *Senior Vice President, Intellectual Property, Regenxbio*

Lauren Foster, *Associate Director, Technology Licensing Office, Massachusetts Institute of Technology*

Sheridan Miyamoto, *Assistant Professor, Principal Investigator, SAFE-T Center, Penn State University*

Mita Mukherjee, *Associate General Counsel, Intellectual Property, Emergent BioSolutions*

Mark Rohrbaugh, *Senior Advisor for Technology Transfer, National Institutes of Health*

Dick Wilder, *General Counsel, Coalition for Epidemic Preparedness Innovations*

Coruzzi and Mukherjee were asked to rank the importance of licensing and collaboration at each stage of development (e.g. research, manufacturing, life cycle trial) and identify places of improvement in this process. Corruzi stated that collaboration is crucial at every stage since different competencies are required for success in each stage. Licensing can greatly expand capacity because companies can license a technology out if they don't have the bandwidth to maximize its potential. At her own company [Regenxbio], they run clinical trials and programs themselves but also license to 15 other companies to perform more comprehensive research using their technology. Mukherjee agreed that licensing is vital at every stage and that collaboration is essential for every company. She added that IP is a mechanism which is the catalyst for and helps to structure collaborative relationships.

Foster focused on the mechanisms that those in the fields of information technology within life sciences use for innovation, particularly referring to exclusive and nonexclusive licensing. Foster stated that there is typically exclusive licensing for therapeutics but there is nuance to the concept of exclusivity. A commercial exclusive license allows other entities to continue to use a product but the original patent holder still holds exclusive rights in terms of further product development. The primary objective is typically to not restrict access but to preserve ownership for the original entity. Sometimes the type of partnership being entered into can influence the scope of licensing partnerships.

Rohrbaugh addressed whether or not the NIH had a different approach than that of MIT (previous answer). At NIH, scientists often enter into cooperative research and development agreements which allows for exclusive licensing for collaboration. Rohrbaugh then spoke about how frequently the NIH receives comments or objections when they publish an exclusive license in the federal register. They do not often receive objections but do occasionally receive comments. In the event, they receive objections they will try to settle the dispute internally.

Wilder addressed the way that the Coalition for Epidemic Preparedness Innovations enables the creation of new technologies and innovation. Wilder's company engages with universities and startups in the early stages of innovation. They assist these entities in creating project plans and protocols for the creation of a specified final product, most likely a therapeutic. They don't have any ownership interests and are mainly focused on ensuring that the research and development project is successful and that the creator gains IP rights.

Miyamoto discussed her experience with navigating the licensing and patent systems from the perspective of a university researcher. Miyamoto credited the Office of Technology Management at Penn State as well as university sponsored tech tournaments for introducing her to IP and steering her through the process of compliant research and development.

Coruzzi later commented on the uncertainty of patents and the judicial precedents for patent litigation. Coruzzi agreed with the points made by Judge Michel the previous day in that the Section 101 standards were being improperly applied. For example, in 1980 the Supreme Court ruled that genetically engineered microbes could be patented which created the biotech and biologic industries. However, later the court held that natural products were not eligible to be patented which stifled investments in these industries and now the U.S. is behind in the creation of the diagnostics that were born from these industries.

Session VI: How Do Regulation and Antitrust Enforcement Impact Competition and Incentives for Innovation

In this session, presenters discussed the extent to which regulation and antitrust enforcement are necessary to maintain competition among safe and effective products, which can impact the incentives for innovation. They also touched on the tradeoffs of antitrust enforcement and regulation in terms of the incentives for innovation during a pandemic.

Moderator: **Alexander Okuliar,** *Deputy Assistant Attorney General, Antitrust Division, DOJ*

Presenters:

Alden Abbott, *General Counsel, Federal Trade Commission*

Ernst Berndt, *Louis E. Seley Professor in Applied Economics, Emeritus, Alfred P. Sloan School of Management, MIT*

David J. Kappos, *Partner, Cravath, Swain, and Moore, LLP*

William Kovacic, *Global Competition Professor of Law and Policy, George Washington University Law School*

Dick Wilder, *General Counsel, Coalition for Epidemic Preparedness Innovations*

Berndt commented on the tradeoffs that may exist between antitrust, IP, and innovation. Berndt found that there were tradeoffs between the three institutions and the impact of such tradeoffs vary. One such tradeoff being that if there are policies such as market exclusivity that prevent markets from emerging or if there is no generic product because of a patent held by a reference product then the possibility of competition is eliminated.

Kappos explored the shortcomings of the current patent system primarily due lack of clarity in eligibility guidance. The lack of clarity is risky for investors. Smaller businesses have much more difficulty attaining patents due to lack of financial backing in the research and development phase. Venture capital funding has plummeted in key technology areas such as drug discovery, pharmaceuticals and surgical devices.

Wilder touched on the incentives that may be needed in order to spur innovation in light of the pandemic and what existing incentives have been successful and those that have failed. Wilder manages 9 vaccine development companies and has seen the process by which companies can gain exclusivity and patents be sped up. However, the speed at which this is being done is concerning. Many processes which previously happened sequentially are happening concurrently. For example, companies are creating manufacturing strategies while still in the research development phase which is alarming because the appropriate oversight to ensure these movements are made wisely does not exist in the same capacity.

Kovacic discussed the roots of the historically contentious relationship between IP and Antitrust. He noted that in the 1930s, the DOJ noticed that patent licensing was being abused by domestic and foreign enterprises to monopolize industries. As a result, they executed a somewhat anti-IP agenda where all incidences of companies receiving clusters of patents was viewed as anticompetitive. However, in recent years as issues of patent bundling have been proven to not be anticompetitive, the relationship between the two factions has been more harmonious.

Abbott built upon Kovacic's points stating that licensing restrictions were prevalent until clearer guidelines were released by the DOJ in the 1970s. These guidelines were further strengthened in 1995 when the DOJ began to apply the same analysis of conduct regarding IP as they would any other type of property rights, stopped presuming that IP rights inherently create market power for a company and recognize that IP licensing allows firms to combine different factors of production and could actually be viewed as procompetitive. Nevertheless, additional headway must be made in the life sciences sector. The parameters of competition are different in this industry and should be evaluated on a case by case basis instead of by adhering to broad guidelines.

Session VII: Competition and Collaboration: Examining Competitive Effects and Antitrust Risks Associated with Collaborations

In this session, participants discussed what makes a collaboration or partnership successful and procompetitive; antitrust concerns that can arise; and potential safeguards that reduce antitrust risk.

Moderator: ***Jennifer Dixton,*** *Special Counsel for Policy and Intellectual Property, Antitrust Division, DOJ*

Presenters:

William Diaz, *Senior Counsel, Amgen*

Andrew Finch, *Partner, Paul Weiss*

Luba Greenwood, *Lecturer in Engineering Sciences, Harvard University*

Chuck Louglin, *Partner, Hogan Lovells*

Finch began the conversation by discussing how a joint venture in the life sciences sector could be successful and procompetitive. He remarked that when companies integrate complementary efficiencies they can increase their output, innovation and get quality products on the market faster. He noted the importance of defining clear boundaries for success. It is critical for companies to establish restrictions for the scope and nature of their partnership to avoid potential antitrust issues. He applauded the capacity for joint ventures in the life sciences industry to connect people with big ideas to people who can execute those ideas which creates a public benefit.

Diaz agreed with Finch's sentiments; adding that joint ventures help to mitigate some of the risk associated with the high failure rates in regard to product development in the life sciences sector by driving down costs. Diaz also touched on the most significant steps in antitrust analysis and how companies can navigate the process. Diaz found that every step is critical but the pre-analysis phase is of the utmost importance. It is critical to assess the market share of the parties and their assets early on to identify the likelihood that the joint venture would even be approved. After this is done, it is easier to determine the intent of the collaboration and its positive impact on the market as a whole.

Loughlin examined the importance of drafting documents of the joint venture that are very specific. Oftentimes companies find themselves in violation of antitrust guidelines inadvertently because the documents governing a joint venture do not adequately specify what behaviors are appropriate and inappropriate. He advised that companies consistently consult with counsel to eliminate any ambiguity to ensure that all players in the joint venture understand and can comply with the given boundaries.

Greenwood shared the experiences that a smaller biotech company might have when collaborating with a larger pharmaceutical company. Greenwood noted that there was previously a significant amount of joint ventures and acquisitions of this type at later stages of research development but returns on these investments have dwindled. As a result, pharmaceutical companies have become efficient at producing innovation at lower costs; so smaller companies expect to allow pharmaceutical companies to acquire their technology much earlier in the research and development process. This alleviates overall costs for smaller companies and allows them to continue to innovate without concern of the financial burden that failure in a later stage of research and development might create.

Lastly, each presenter was asked to comment on what the Department of Justice could do to address uncertainty in the guidelines for joint ventures as they are 20 years old and may not reflect contemporary trends. Greenwood noted that there is much uncertainty because the nature of assets is different in this arena. For example, personalized medicine creates subdivisions of care and some companies are dominating certain subdivisions with impunity. Therefore, additional guidance is needed to address and prevent these behaviors. Finch agreed that the competitor guidelines are vague and could use a refresher due to their age. Loughlin called for an update to the illustrative examples in the guidelines and to include sections that are dedicated to the interpretation of the guidelines for specific industries such as the life sciences sector.

Keynote Speech:

Dr. Elias A. Zerhouni, *Emeritus Professor of Radiology and Biomedical Engineering and Senior Advisor, Johns Hopkins Medicine*

Dr. Zerhouni discussed the notable amount of development in the areas of bacteria and infectious diseases and the role that patents and integration have played in that development. The novel coronavirus pandemic has exemplified how much work has been done in this area since scientists have been able to rely heavily on America's stockpile of previously researched and patented compounds and therapeutics as they search for treatments, cures, and vaccines. Additionally, the role of collaboration cannot be understated. Companies have varying capacities and resources. It is rare for a single company to possess all of the components necessary to perform pharmaceutical or vaccine development. It is vital for companies to integrate horizontally in order to optimize their strengths so new therapies can be introduced to the market. The relationship between intellectual property and collaboration has been abundantly clear this year as we look to use these mechanisms to quell the pandemic.