

UNITED STATES PATENT AND TRADEMARK OFFICE

USPTO-FDA PUBLIC LISTENING SESSION

Alexandria, Virginia

Thursday, January 19, 2023

1 PARTICIPANTS:

2 Held Before:

3 LINDA HORNER  
Administrative Patent Judge

4 KATHERINE K. VIDAL  
5 Under Secretary of Commerce for Intellectual  
Property and Director of the United States Patent  
6 and Trademark Office

7 DR. ROBERT M. CALIFF  
Commissioner of Food and Drugs  
8 United States Food and Drug Administration

9 Session 1: Patient Perspectives:

10 Speakers:

11 LESLIE RITTER  
National Multiple Sclerosis Society

12 SNEHA DAVE  
13 Generation Patient

14 Panelists:

15 JACQUELINE BONILLA  
U.S. Patent and Trademark Office

16 LINDA HORNER  
17 U.S. Patent and Trademark Office

18 ZAHAVA HURWITZ  
U.S. Food and Drug Administration

19 DANIEL RITTERBECK  
20 U.S. Food and Drug Administration

21

22

1 PARTICIPANTS (CONT'D):

2 Session 2: Examiner Training on Publicly  
3 Available FDA Resources:

3

4 Speaker:

4

5 KEVIN WREN  
6 TInternational

6

7 Panelists:

7

8 DANIEL SULLIVAN  
9 U.S. Patent and Trademark Office

8

9 DANIEL KOLKER  
10 U.S. Patent and Trademark Office

10

11 BETHANY BARHAM  
12 U.S. Patent and Trademark Office

11

12 ZAHAVA HURWITZ  
13 U.S. Food and Drug Administration

12

13 DANIEL RITTERBECK  
14 U.S. Food and Drug Administration

14

15 Session 3: Applicant Statements Made to USPTO and  
16 FDA:

16

17 Speakers:

17

18 PROFESSOR ROBIN FELDMAN  
19 University of California Hastings College of  
20 the Law

18

19 TAHIR AMIN  
20 Initiative for Medicines Access & Knowledge  
(I-MAK)

19

20

21 HANS SAUER  
22 Biotechnology Innovation Organization (BIO)

21

22

1 PARTICIPANTS (CONT'D):

2 SHAINA KASPER  
3 TlInternational

4 PROFESSOR ADAM MOSSOFF  
5 George Mason University, Antonin Scalia Law  
6 School

7 CAROL NIELSEN  
8 Nielsen IP Law, on behalf of American  
9 Intellectual Property Law Association

10 Panelists:

11 ALI SALIMI  
12 U.S. Patent and Trademark Office

13 KARIN FERRITER  
14 U.S. Patent and Trademark Office

15 MARY TILL  
16 U.S. Patent and Trademark Office

17 LINDA HORNER  
18 U.S. Patent and Trademark Office

19 MARIANNE TERROT  
20 U.S. Food and Drug Administration

21 KRISTIN DAVIS  
22 U.S. Food and Drug Administration

MUSTAFA UNLU  
U.S. Food and Drug Administration

DANIEL RITTERBECK  
U.S. Food and Drug Administration

Session 4: Patenting Practices in the  
Pharmaceutical Sector:

Speakers:

1 PARTICIPANTS (CONT'D):

2 JULIANA REED  
Biosimilars Forum

3  
4 DAVID KORN  
PhRMA

5 PROFESSOR LIZA VERTINSKY  
6 University of Maryland Francis King Carey School  
of Law

7 DR. S. SEAN TU  
8 West Virginia University College of Law

9 SARAH BOURLAND  
Patients for Affordable Drugs

10 COREY SALSBERG  
Novartis

11 AZEEN JAMES  
12 Fresenius Kabi

13 Panelists:

14 ROBIN EVANS  
U.S. Patent and Trademark Office

15 KARIN FERRITER  
16 U.S. Patent and Trademark Office

17 MINNA MOEZIE  
U.S. Patent and Trademark Office

18 MARIANNE TERROT  
19 U.S. Food and Drug Administration

20 KRISTIN DAVIS  
U.S. Food and Drug Administration

21 MUSTAFA UNLU  
22 U.S. Food and Drug Administration

1 PARTICIPANTS (CONT'D):

2 DANIEL RITTERBECK  
3 U.S. Food and Drug Administration

4 Session 5: Patent Term Extension and Patent Use  
Codes:

5 Speakers:

6 VICTOR VAN de WIELE  
7 Harvard Medical School

8 EMMABELLA RUDD  
9 TlInternational

10 PATRICIA KELMAR  
11 U.S. Public Interest Research Group (U.S. PIRG)

12 PROFESSOR JOHN R. THOMAS  
13 Georgetown University Law Center

14 Panelists:

15 ALI SALIMI  
16 U.S. Patent and Trademark Office

17 MARY TILL  
18 U.S. Patent and Trademark Office

19 LINDA HORNER  
20 U.S. Patent and Trademark Office

21 MARIANNE TERROT  
22 U.S. Food and Drug Administration

KRISTIN DAVIS  
U.S. Food and Drug Administration

MUSTAFA UNLU  
U.S. Food and Drug Administration

1 PARTICIPANTS (CONT'D):

2 DANIEL RITTERBECK  
3 U.S. Food and Drug Administration

4

Closing Remarks:

5

DERRICK BRENT  
6 Deputy Under Secretary of Commerce for  
Intellectual Property and Deputy Director  
of the United States Patent and Trademark  
Office

7

8

9

10 \* \* \* \* \*

11

12

13

14

15

16

17

18

19

20

21

22

## 1 C O N T E N T S

2	Item	Page
3	Welcome and Introductions	
4	Opening Remarks: Dr. Robert M. Califf	
5	Opening Remarks: Katherine K. Vidal	
6	Announcements	
7	Session 1: Patient Perspectives	
8	Session 2: Examiner Training on Publicly	
9	Available FDA Resources	
10	Session 3: Applicant Statements Made to USPTO and	
11	FDA	
12	Session 4: Patenting Practices in the	
13	Pharmaceutical Sector	
14	Session 5: Patent Term Extension and Patent Use	
15	Codes	
16	Closing Remarks	

15

16

17

\* \* \* \* \*

18

19

20

21

22



1 P R O C E E D I N G S

2 (10:01 a.m.)

3 JUDGE HORNER: Good morning and welcome  
4 to the Joint Listening Session cohosted by the  
5 United States Patent and Trademark Office and the  
6 U.S. Food and Drug Administration. My name is  
7 Linda Horner. I'm an administrative patent judge  
8 here at the USPTO. And I've been working  
9 alongside my counterparts at the FDA to lead a  
10 collaborative interagency team to advance  
11 President Biden's Executive Order on Promoting  
12 Competition in the American Economy.

13 I will serve as moderator for today's  
14 listening session. And the purpose of the  
15 listening session is to provide an opportunity for  
16 broad public input on proposed initiatives for  
17 collaboration between the agencies. I'll provide  
18 a few announcements shortly. But before we begin,  
19 we have two distinguished guests here with us this  
20 morning to deliver opening remarks.

21 Dr. Robert M. Califf was confirmed last  
22 year as the 25th Commissioner of Food and Drugs.

1       He also served in 2016 as the 22nd Commissioner.  
2       And immediately prior to that as the FDA's Deputy  
3       Commissioner for Medical Products and Tobacco. He  
4       spent a good portion of his career affiliated with  
5       Duke University where he served as a professor of  
6       medicine and vice chancellor for clinical and  
7       translational research. He was director of the  
8       Duke Translational Medicine Institute and was the  
9       founding director of the Duke Clinical Research  
10      Institute.

11               Dr. Califf has had a long and  
12      distinguished career as a physician, researcher,  
13      and leader in the fields of science and medicine.  
14      He is a nationally recognized expert in  
15      cardiovascular medicine, health outcomes research,  
16      healthcare quality, and clinical research, and a  
17      leader in the growing field of translational  
18      research, which is key to ensuring that advances  
19      in science translate into medical care.

20               Kathi Vidal serves as the Under  
21      Secretary of Commerce for Intellectual Property  
22      and the Director of the United States Patent and

1 Trademark Office. As the Chief Executive of the  
2 USPTO, she leads one of the largest intellectual  
3 property offices in the world with more than  
4 13,000 employees and an annual budget of nearly 4  
5 million.

6 She's the principal IP advisor to the  
7 President and the administration through the  
8 Secretary of Commerce and is focused on  
9 incentivizing and protecting U.S.  
10 Entrepreneurship, innovation, and creativity, and  
11 helping American workers and businesses compete  
12 and collaborate, especially in key technology  
13 areas and across demographics. Director Vidal  
14 also is working to expand American innovation for  
15 and from all, including serving as the vice chair  
16 of the Council for Inclusive Innovation,  
17 CI-Squared, along with Secretary of Commerce, Gina  
18 M. Raimondo, and the council members.

19 And with those introductions, please  
20 welcome Commissioner Califf to the podium for his  
21 opening remarks.

22 DR. CALIFF: Thank you so much, Linda.

1 And I do want to note that I have a lot of work to  
2 do in D.C. and Silver Spring today so I put on my  
3 Maryland bow tie, which you heard I'm a longtime  
4 Duke person. It's very difficult to wear a  
5 Maryland bow tie. And then on the way over, Emily  
6 told me wait a minute, you're going to Virginia.  
7 It's not going to be well received there either.  
8 But as I meet with many politicians, I'm trying to  
9 collect bowties to represent every state so I can  
10 be user-friendly as I go.

11 And also, just in light of this  
12 conference, hearing, reminded about my credentials  
13 as a cardiologist, I think it is worth a moment  
14 just to reflect on the wonders of technology and  
15 what can happen when it's used well. I'm sure all  
16 of you have followed the saga of the Buffalo Bills  
17 football player and if you just think about what  
18 happened in that very brief period of time to go  
19 from a full cardiac arrest to defibrillation and  
20 now a person who's out and about doing fine.

21 It's just an amazing -- and you think  
22 about all the steps that people like you were

1       involved in going from the idea of a technology of  
2       external defibrillation to a defibrillator that  
3       can be kept anywhere in the country and used by  
4       novices really effectively. I think it's a real  
5       testament to what can be done if we do our jobs  
6       well in combination with so many creative people  
7       in the industries.

8               So, I am delighted that USPTO and the  
9       FDA are collaborating in this joint listening  
10      session, as well as in many other ways. And I  
11      want to express my gratitude for all that the  
12      employees from both agencies who I know have been  
13      working for many months to lay the groundwork and  
14      prepare for today's meeting. These meetings  
15      involve a lot of preparation. So, thank you. I  
16      also want to thank the many product developers,  
17      representatives of industry, academia, and  
18      consumer organizations, as well as the patient  
19      advocates, and other stakeholders who are  
20      participating today, and for your continuing  
21      involvement in these issues.

22             As President Biden recognized in his

1       2021 Executive Order on Promoting Competition, our  
2       two agencies have distinct authorities and  
3       missions. In a number of key areas, however, when  
4       it comes to efforts to make essential prescription  
5       drugs more affordable and accessible to the  
6       patients who need them, we have some important  
7       overlapping and complementary interests and  
8       responsibilities.

9               I will note here also having worked in  
10       academia and in private industry, matrix  
11       interactions don't come naturally in government,  
12       I've learned. And so, I'm really proud that this  
13       I hope will be a great continuing example of  
14       working across agencies in a more effective way on  
15       both sides.

16              So, since the issuance of this executive  
17       order, FDA and USPTO have been working together to  
18       leverage our combined expertise. For instance,  
19       we've begun interagency cross- training to help  
20       strengthen our understanding of our respective  
21       responsibilities and how we can work together.  
22       Today's public listening session is the latest

1 chapter in this continuing effort designed  
2 specifically to provide stakeholders with the  
3 opportunity to speak with both agencies at the  
4 same time about these vital issues.

5 As a public health agency, the FDA has  
6 the responsibility to use the best available  
7 science to review new medical products to  
8 determine whether they're safe and effective for  
9 specific indications so that the balance of risks  
10 and benefits for use of those indications, makes  
11 them suitable for marketing. But there's another  
12 important related, though perhaps less well-known  
13 aspect of our work, that is to encourage the  
14 scientific research and development during the  
15 long course from concept to determination of  
16 approvability to help ensure they're translated  
17 into meaningful products that can make a  
18 difference for patients.

19 This responsibility extends for the  
20 entire product lifecycle, well beyond the patent  
21 life. To this end, the FDA has a number of robust  
22 programs to advance the development, approval, and

1 marketing of high-quality generics and  
2 biosimilars. For instance, the science and  
3 research program established under the Generic  
4 Drug User Fee Amendments, or GDUFA, helps us  
5 provide product-specific guidance to support  
6 generic drug development. Likewise, FDA has  
7 initiated a regulatory science program pilot under  
8 the Biosimilar User Fee Act, or BSUFA, that  
9 focuses on advancing the development of  
10 interchangeable biosimilar products and improving  
11 the efficiency of biosimilar product development.

12 Both programs also have mechanisms for  
13 FDA to communicate with applicants early in the  
14 process to help clarify regulatory expectations  
15 for prospective applicants. These early  
16 communications help make product review more  
17 efficient by proactively addressing emerging  
18 scientific and regulatory issues and thereby  
19 reduce a generic or drug or biosimilar product's  
20 time in the pipeline from concept to development  
21 to market.

22 We're also focused on supporting the



1 development of complex generic drugs such as  
2 products with complex active ingredients or drug  
3 device combination products. These products are  
4 critical to the treatment of many medical  
5 conditions. But because they can be more  
6 scientifically challenging, time consuming, and  
7 expensive to develop they often lack adequate  
8 generic competition. In addition, there can be  
9 greater uncertainty concerning the approval  
10 pathway or questions on issues such as proposed  
11 study designs or possible alternative approaches.

12 We know the importance in America's  
13 place on affordable prescription drugs. Generic  
14 drugs today represent nine out of 10, or 90  
15 percent, of all prescriptions that are filled.  
16 What this means is that more patients have greater  
17 access to affordable, safe, effective, and  
18 high-quality medicines. And that patient access  
19 continues to be a priority for the FDA.

20 While our agency doesn't play a direct  
21 role in drug pricing, we can, by encouraging  
22 development of generic and biosimilar products,

1 support increased competition in the healthcare  
2 market. This can have a transformative impact by  
3 improving affordability and increasing access to  
4 these essential medicines.

5 On a personal level, I'm certainly glad  
6 I get important medications I need for things like  
7 blood pressure and lipid control in a generic  
8 form. At age 71, like most seniors, I'm on a  
9 number of medications and it's really good to have  
10 these low-price generics that I can have  
11 confidence in. And I think it's a fair deal to  
12 have access to low-cost versions of these  
13 medicines after a defined period of protection.

14 And that's the crux of the matter. Our  
15 laws and regulations provide drug developers with  
16 protection from competition for a specific period  
17 of time. The reason for this is that these  
18 companies do necessary and important research in  
19 support of their development of essential and  
20 often lifesaving treatments. Consequently, they  
21 should be allowed to recoup and benefit from their  
22 investments. That code of fairness is why these

1 principles were written into law.

2           At the same time, however, delay in  
3 competition must have limits and involve a balance  
4 between innovation and access. The just rewards  
5 that come with investment in R&D must be balanced  
6 with legal and regulatory pathways that allow for  
7 and encourage generic drug and biosimilar product  
8 manufacturers to enter the market. This helps  
9 increase competition and drive down prices,  
10 thereby making these essential drugs more  
11 accessible and affordable and lowering healthcare  
12 costs. Moreover, by enabling a path for  
13 competition, we provide developers and innovators  
14 with added incentive to invest in further research  
15 that will lead to the discovery of new drugs that  
16 can deliver additional benefits for patients.

17           As you're probably aware, there are  
18 significant savings to consumers from this kind of  
19 competition. In 2022, the FDA estimated the cost  
20 savings from new generic approvals from 2018 to  
21 2020 amounted to \$53.3 billion a year. It's worth  
22 noting that first generic approvals accounted for

1       about one-third, or exactly 29 percent, of these  
2       total savings. First generics are especially  
3       important because they are the first approval by  
4       the FDA that permits an application holder to  
5       market a generic drug product in the United  
6       States.

7               While this system is sensible and  
8       straightforward, the road to competition requires  
9       sponsors to navigate both the drug approval  
10      process and intellectual property issues before  
11      generic and biosimilar products can be brought to  
12      market. For example, under the Hatch-Waxman law,  
13      many first generics only obtain final approval  
14      after they have challenged a patent listed in the  
15      Orange Book for the brand product based on the  
16      generic applicant's opinion that the patent is  
17      invalid, unenforceable, or will not be infringed  
18      by the generic product.

19             Unfortunately, we also have seen gaming  
20      tactics by some brand companies who attempt to  
21      impede or undercut competition from generics and  
22      biosimilars. We put in place multiple

1 comprehensive initiatives, many of which are  
2 outlined in the Drug Competition Action Plan and  
3 the Biosimilars Action Plan, aimed at reducing the  
4 so-called gaming of FDA regulations that attempts  
5 to extend brand monopolies beyond what Congress  
6 intended with Hatch-Waxman and unfairly delay  
7 market competition.

8           These plans also include policies that  
9 improve the efficiency of the FDA's review of  
10 marketing applications for generics, biosimilar,  
11 and interchangeable products, increased scientific  
12 clarity, and regulatory certainty for  
13 manufacturers and other stakeholders, and help  
14 educate stakeholders about interchangeable  
15 products. The objective of our two agencies'  
16 collaboration under the executive order is to  
17 ensure the patent system is not used in ways that  
18 unjustifiably delay generic drugs and biosimilar  
19 competition beyond that reasonably contemplated by  
20 law.

21           While FDA only has a ministerial role  
22 when it comes to patents and their listing in the

1 Orange and Purple Books, collaboration between our  
2 agencies remains important. We're committed to  
3 working with PTO on the initiatives and topics  
4 outlined in our exchange of letters, as well as to  
5 working with other federal partners like the  
6 Federal Trade Commission to advance competition  
7 and ensure enforcement of the laws.

8           There's one other important point I  
9 think worth noting that's increasingly been coming  
10 to my attention. That's the potential problem of  
11 prices being driven too low to give manufacturers  
12 incentives to continue to produce drugs for  
13 certain markets. We know, for instance, that when  
14 more than 95 percent of the market for a  
15 particular product is filled with generics, that  
16 saturation can result in manufacturers leaving the  
17 market.

18           This is not an issue related to patent  
19 law as these products typically have been off  
20 patent for a long time. But what it makes clear  
21 is that the problem of access to affordable  
22 medications in the marketplace will not be solved

1 simply by encouraging and introducing competition.  
2 It must also include consideration of other  
3 issues, including how to provide incentives for  
4 manufacturers to continue to supply less  
5 profitable off-patent drugs in the long term. We  
6 need to ensure that market competition and the  
7 resilience of the supply chain are promoted and  
8 sustained even after generics and biosimilars are  
9 on the market.

10 The USPTO and the FDA will continue to  
11 collaborate in the development of policies aimed  
12 at protecting and promoting U.S. innovation,  
13 advancing competition, and lowering prescription  
14 drug prices for all Americans. We must achieve  
15 the appropriate balance that encourages meaningful  
16 innovation of drug development, while not unduly  
17 delaying competition that provides relief from the  
18 high costs of medicines.

19 I want to thank you again for your  
20 engagement and we look forward to your comments  
21 and questions today and going forward. I wish I  
22 could be here for the whole meeting, but there are

1 a number of other issues I have to attend to and  
2 we have so many FDA people, I'm sure I'll get a  
3 complete report of what was said and much  
4 appreciate the chance to be here.

5 DIRECTOR VIDAL: Thank you, Commissioner  
6 Califf. I will say that one of the first things I  
7 noticed when the Commissioner came in here was his  
8 bow tie. I asked him if he has a Virginia one.  
9 He does not. He said it's hard to find. So, I'm  
10 going to go set forth trying to find him one.

11 I want to thank you for all the work  
12 that we're doing together, both with your staff  
13 and the work that you and I do together directly,  
14 and for being so accessible when we have issues  
15 we're trying to resolve and it requires us to have  
16 a one-on-one conversation. So, I appreciate that.

17 And I do want to thank your staff. I  
18 want to let everybody here know that we do have  
19 staff both from the USPTO and the FDA. Can the  
20 staff from the FDA raise their hand or identify  
21 themselves so people can see where you are?  
22 Wonderful. Thank you so much for all of your



1 collaboration with our teams and for all the great  
2 work you're doing.

3 I also want to thank Linda. Thank you  
4 for your opening remarks. And thank you for  
5 leading the initiative at the USPTO. I know that  
6 you're working tirelessly on these issues. I know  
7 the entire team is. So, I want to thank you and  
8 our team. If the USPTO representatives could  
9 raise their hand, that would be great. A lot of  
10 enthusiasm there today. I think we maybe need to  
11 refill that coffee.

12 So, I also wanted to take this  
13 opportunity to introduce the USPTO's new  
14 Commissioner for Patents, Vaishali Udupa. Because  
15 the work that she is going to be doing is going to  
16 be critical to everything we're discussing today.  
17 So, Vaishali, if you could stand and actually,  
18 maybe come up on stage just because I know we have  
19 so many people attending remotely.

20 Commissioner Udupa was just sworn in  
21 two, three days ago?

22 COMMISSIONER UDUPA: This is day three

1 on the job.

2 DIRECTOR VIDAL: This is day three on  
3 the job. She has a technical background and is a  
4 nationally recognized leader in intellectual  
5 property with over 20 years' of experience in  
6 strategic IP advisement and complex litigation.  
7 The best story about her that I love is she  
8 applied to be a patent examiner 26 years ago.  
9 This is where she always wanted to be. At the  
10 time she happened to not be a citizen yet. So, we  
11 couldn't take her on then. But she's been working  
12 hard to be in the USPTO ever since. So, just that  
13 dedication, that commitment to public service, and  
14 to working on behalf of the country as the  
15 ultimate client is just phenomenal.

16 She has a wealth of experience in patent  
17 prosecution, licensing, and litigation, including  
18 developing patent and trademark portfolios,  
19 national and global IP policy, and diversity,  
20 equity, inclusion, and accessibility. And like  
21 me, when we talk about inclusion, it's everybody.  
22 Commissioner Udupa is going to be working with me

1       this week on our Robust and Reliable Patent  
2       Initiatives. That was one of the initiatives that  
3       we mentioned in the letter that I sent to  
4       Commissioner Califf.

5               We have already released one request for  
6       comment on the Robust and Reliable Patents. If  
7       you haven't seen it, comments are due February 1.  
8       And we are working on a second one that the  
9       Commissioner and I will be working on. So, on  
10      behalf of everyone at the USPTO, and I'm sure  
11      everybody in this room, we want to welcome you to  
12      America's innovation agency. Thank you.

13             COMMISSIONER UDUPA: Thank you.

14             DIRECTOR VIDAL: Accessibility to  
15      medicine for all Americans is a top priority of  
16      this administration. It is not only a moral  
17      imperative; it is a national one. The U.S. is a  
18      leader in innovation in the pharmaceutical space  
19      in large part because of our patent system. The  
20      patent system plays a critical role in the  
21      development of new and innovative medicines. It  
22      incentivizes the research and development that is

1       necessary to bring these products to market. And  
2       it incentivizes the disclosure that is necessary  
3       so that others can build on innovation.

4               And the generic market relies on that  
5       system because as we get products out there,  
6       people can continue to build on them. I'm often  
7       asked what my views are on the pharmaceutical  
8       space. And I don't think I articulated it any  
9       better than the letter I sent on July 6 to  
10      Commissioner Califf. So, I just want to read a  
11      few short lines from that. I would also encourage  
12      everybody here if you have not read the letter, it  
13      really outlines a lot of the work that the USPTO  
14      is doing in this space and the work that we're  
15      doing in collaboration with the FDA.

16             So, from the letter. The patent system  
17      was developed to promote economic growth and a  
18      higher standard of living for all. The United  
19      States is a global leader in new drug development  
20      due to its strong system and the ecosystem  
21      envisioned by Congress with the Drug Price  
22      Competition and Patent Term Restoration Act. As

1     you all know, the Hatch- Waxman Act of 1984, and  
2     more recently the Biologics Price Competition and  
3     Innovation Act.

4             Though patents play a critical role in  
5     incentivizing and protecting the investment  
6     essential for bringing lifesaving and life  
7     altering drugs to market, we must make sure our  
8     system as a whole does not unnecessarily delay  
9     generic, biosimilar, and more affordable versions  
10    of those drugs getting into the hands of Americans  
11    who need them.

12            In addition to all of the different  
13    ideas that I outlined in this letter, with the  
14    help of Linda and our entire team, the USPTO has  
15    several programs to try and incentivize investment  
16    in the medical space. We have a COVID-19  
17    Prioritized Examination program that will continue  
18    until there is no longer a crisis. That allows us  
19    to expedite patents in that space so we can get  
20    products to market more quickly. We also have a  
21    Cancer Moonshot Expedited Examination program that  
22    will be starting on February 1.

1           We also recognize that improperly issued  
2       patents extract a cost on society. At the USPTO,  
3       you can come back and challenge patents that we  
4       have issued through our Patent Trial and Appeal  
5       Board. As soon as I came onboard, I tried to  
6       clarify some of the rules on when we would take on  
7       those challenges and when we would, under the  
8       Director's discretion, deny -- discretionarily  
9       deny those challenges. And one of the first  
10      changes I made was to institute a new standard of  
11      compelling evidence of patentability because there  
12      were some concerns that we were discretionarily  
13      denying strong challenges that we should be  
14      looking at.

15           I've issued guidance under this. We are  
16      going in 2023 to work on rulemaking. So, I would  
17      encourage you to stay apprised of that. Please  
18      provide your comments as we move forward because  
19      we're looking forward to making the system work  
20      for everyone. I'll also note that in one of my  
21      many roles, I also comment on Supreme Court cases.  
22      And sometimes I pick up the phone or email

1 Commissioner Califf on some of those where the  
2 cases intersect the work that we're doing.

3 I was asked recently if it was worth  
4 providing -- I was asked I think this week, on  
5 whether it's worth providing comments on our RFCs,  
6 and submitting amicus briefs, and doing all that  
7 hard work. I will tell you it's incredibly  
8 important to the work that I do. I do need to  
9 hear from everyone. Our team summarizes comments,  
10 but I go back through and read a lot of them  
11 individually. And any time I go to make a  
12 decision, whether it's collaborating on a position  
13 the U.S. should take on a Supreme Court case, or  
14 whether it's on regulations that we are going  
15 promulgate within the USPTO, I always go back and  
16 read dissenting views to make sure that wherever  
17 we're landing the plane, it's in the right place.

18 Now, we recognize that our agencies do  
19 not have all the answers. I think you heard some  
20 of that from Commissioner Califf. But we're doing  
21 what we can within our power. That's why we're  
22 excited to hear from all of you today. I want to

1     thank all the speakers who have taken the time. I  
2     want to thank all of those who submitted comments.  
3     I know it's a lot of work. I know especially when  
4     you work within companies and organizations,  
5     there's a lot of vetting, a lot of back and forth.  
6     And I can only imagine the immense effort you  
7     committed to today.

8             We will hear today from patients, from  
9     public interest advocates, from academics, from  
10    industry groups, from brand pharmaceutical, and  
11    generic companies, and brand biotech, and  
12    biosimilar companies. So, thanks to all of you  
13    and thank you to everybody who's tuning in today.  
14    We will also hear from subject matter experts from  
15    the USPTO and FDA that you heard from recently.

16            Through all of your hard work, we are  
17    going to take the input that you're providing both  
18    through your comments and through the work that  
19    you're doing with the submissions to create  
20    positive impact on accessibility to lifesaving and  
21    life altering medications. So, thank you for  
22    being here. And with that I will turn it over so



1       we can begin our discussion. I will note that I  
2       plan to listen in to all of this from my office.  
3       I may come down during the breaks. But I'm  
4       looking forward to hearing from all of you  
5       directly. Thank you.

6               JUDGE HORNER: Thank you, Commissioner  
7       Califf and Director Vidal, for being here today  
8       and for your remarks and leadership. Your  
9       insights will frame the discussions that are to  
10      follow. We know you have busy schedules and we're  
11      going to let you get on with the rest of your day.

12             I'm going to take a moment just to  
13      relocate myself to this head table. This is where  
14      the rest of the remarks will be today in the  
15      question-and-answer period. And so, I'll go ahead  
16      and relocate there and then make a few  
17      announcements before we get started with our first  
18      session.

19             Okay. Hopefully, everyone can hear me  
20      okay with my mask on. I'm going to try to leave  
21      it on while I'm at the table here. I wanted to  
22      make a few announcements before we get started.

1 First, if you'd please silence any cell phones or  
2 mobile devices so we don't have interruptions  
3 during the day. Second, we ask that all  
4 attendees, and especially speakers, if you haven't  
5 done so already, sign in at the registration table  
6 so we know you're here. And third, if you're  
7 looking for restrooms during the breaks, they're  
8 just outside the door here, down the hall past the  
9 coffee kiosk.

10 We are recording this event and it's  
11 being transcribed. And we'll post the recording  
12 and the transcript a few weeks, two to three weeks  
13 after the event on the USPTO webpage. I know we  
14 have a few members of the media here today. If  
15 you have media inquiries, Paul Fucito at the USPTO  
16 is our press secretary and you can direct any  
17 media inquiries to Paul. If any members of the  
18 media are here today, please make sure you sign in  
19 so we know you're here. And because the listening  
20 session is intended to give our agencies time to  
21 hear from the public and the panelists, the  
22 panelists and other USPTO and FDA members are not

1       available today to speak with the media or make  
2       statements.

3               Here are some procedural rules for  
4       today. We have 20 speakers today. We've divided  
5       the speakers into topical sessions based on the  
6       primary topic of interest that they indicated in  
7       their registration. Although each session focuses  
8       on the speaker's primary topic of interest, they  
9       are free to comment on any aspect of any of the  
10      inquiries in the Federal Register Notice.

11             No participant can interrupt the  
12      presentation of any other speaker and only the  
13      USPTO and FDA panel members seated here along this  
14      side of the table will be allowed to question the  
15      speakers. At the start of each session, we invite  
16      the speakers for that session and the USPTO and  
17      FDA panel members for that session to move to this  
18      head table and be seated in front of the tent card  
19      with their name on it.

20             I will note here and it's marked in your  
21      agenda, we have a few speakers today appearing  
22      virtually due to requests for special

1 accommodation. And these speakers will appear on  
2 the large screens in the front of the room. Each  
3 speaker will present in the order listed on the  
4 agenda and each will have seven minutes to present  
5 their remarks. After each speaker presents, our  
6 USPTO and FDA panel members will have three  
7 minutes to ask questions of the speaker.

8           If the speaker finishes early or the  
9 panel does not use the full three minutes, we'll  
10 move on to the next speaker. And we will plan to  
11 keep to our scheduled breaks as set out in the  
12 agenda. And for the speakers, we have timer  
13 lights here to guide you. So, green when it's  
14 time for you to speak, yellow when you have one  
15 minute left, and red when your time is up. If  
16 you've not concluded your remarks by the time the  
17 light turns red, I apologize in advance, but I may  
18 interrupt you and tell you your time is up.

19           Please remember that the listening  
20 session is being transcribed and recorded so, when  
21 you come up to speak, use the microphones at the  
22 head table here. You would push the button to

1 talk and you'll see it will light up red when the  
2 mic is hot. And then please turn your mic off  
3 after you finish.

4           Speakers have already submitted their  
5 remarks to the docket on regulations.gov. So, if  
6 you go on that site you should be able to see all  
7 the speakers' remarks. We do invite the speakers,  
8 you're welcome to submit any other thoughts or  
9 input that you have using that same portal. And  
10 the Federal Register Notice has details on how to  
11 submit comments and anyone listening today if you  
12 wish to submit written comments, the docket will  
13 remain open until Monday, February 6th.

14           This hearing is being webcast live.  
15 However, it is not interactive. So, webcast  
16 viewers you won't be able to comment or ask any  
17 questions. But, of course, you can submit written  
18 comments to the docket.

19           So, we're going to start with our first  
20 session. Thank you all for coming. We're already  
21 seated here at the head table and we will have one  
22 speaker today that's virtual. But before we turn

1 to the first speaker, I'd like to ask the USPTO  
2 and FDA folks to introduce themselves with their  
3 name, title, business unit, or department, and  
4 then agency.

5 MS. HURWITZ: Good morning. I'm Zahava  
6 Hurwitz. I'm the Director of the Policy,  
7 Engagement, and Coordination Staff in the Office  
8 of Policy. It's in the office of the Commissioner  
9 at FDA. And our division is the Office of Policy,  
10 Legislation, and International Affairs.

11 MR. RITTERBECK: Good morning, everyone.  
12 My name is Dan Ritterbeck. I am a regulatory  
13 counsel in CDER's Office of Regulatory Policy at  
14 the FDA.

15 JUDGE BONILLA: Hello, good morning.  
16 Thank you, everybody, for coming. My name is  
17 Jackie Bonilla. I am at the USPTO at the Patent  
18 Trial and Appeal Board, Deputy Chief  
19 Administrative Patent Judge there. And I have a  
20 background in pharma as well.

21 JUDGE HORNER: Great, thank you. Our  
22 first panelist is Ms. Leslie Ritter from the

1 National Multiple Sclerosis Society. Ms. Ritter,  
2 you can begin with your remarks.

3 MS. RITTER: Thank you. Good morning.  
4 And thank you for hosting this important listening  
5 session. My name is Leslie Ritter. I am the  
6 Associate Vice President of Federal Government  
7 Relations at the National Multiple Sclerosis  
8 Society. And my goal this morning is to detail  
9 how the misuse of patents and gaming of the  
10 regulatory system ultimately hurts the people who  
11 rely on them the most and make recommendations on  
12 how FDA and the USPTO can work collaboratively to  
13 end these practices.

14 MS is an unpredictable disease of the  
15 central nervous system. Currently, there is no  
16 cure. And symptoms may vary from person to person  
17 and include disabling fatigue, mobility  
18 challenges, cognitive changes, and vision issues.  
19 An estimated 1 million people live with MS in the  
20 United States. And it is also a highly expensive  
21 disease. The total estimated cost to the U.S.  
22 Economy is 85.4 billion per year.

1           Early and ongoing treatment with an MS  
2   disease modifying therapy is the best way to  
3   manage disease course, prevent accumulation of  
4   disability, and protect the brain from damage due  
5   to MS. There are now more than 20 MS DMTs on the  
6   market and these medications have transformed the  
7   treatment of the disease over the past 30 years.

8           Unfortunately, these DMTs are incredibly  
9   expensive. And competitions amongst the brands  
10   have driven prices up rather than down. People  
11   with MS stay on these medications for years with  
12   the annual cost for individuals ranging from  
13   \$57,202 to \$92,719, depending on a person's age or  
14   gender. Although there are now lower cost  
15   options, including generic options for some MS  
16   DMTs, they are still relatively new to the MS  
17   market. And there is currently a submission for  
18   the first MS biosimilar before the FDA.

19           People with MS have waited a long time  
20   for these generics. The first non-biological  
21   medication for MS came on the market in 1997, and  
22   a generic was not available until 2017. This



1       delay in availability of lower cost options and  
2       the high prices of MS medications has a real  
3       impact on people's lives.

4               In a 2019 the National MS Society survey  
5       of people with MS, 40 percent had altered the use  
6       of their DMT with some due to cost, with some  
7       skipping or delaying treatment altogether. And  
8       more than half of those surveyed said that they  
9       were concerned about being able to afford their  
10      DMT in the next few years.

11             People affected by MS have benefited  
12      from and support innovation. Innovation is what  
13      ultimately will get us to a cure. We believe that  
14      it is critical that the U.S. maintain an  
15      environment that allows for the risk needed to  
16      drive research and development of life changing  
17      therapies and innovators should be rewarded and  
18      compensated fairly.

19             The Hatch-Waxman Act provides the  
20      framework that has allowed the U.S. to remain a  
21      leader in medical innovation and works well to  
22      address the multiple goals of innovation,

1     affordability, and promoting competition. Yet,  
2     practices being discussed here today seem to be at  
3     odds with the intent of the Hatch-Waxman Act and  
4     hinder patient access to lower cost therapies.

5             We have seen tactics discussed today  
6     used in the MS market. Brand companies patenting  
7     FDA required brand safety programs and methods  
8     used to monitor a safe therapy engage if it is  
9     working. Some MS DMTs have upwards of 20 patents  
10    associated with just one therapy, often extending  
11    protections from generic competitions for decades.  
12    And brand manufacturers of MS DMTs have made small  
13    tweaks or modifications to drugs already on the  
14    market, thereby extending the patent life of older  
15    products. Then they obtain approval for those  
16    products and move people with MS to that new  
17    product right before the entry of a generic  
18    version of the older drug into the market.

19            These practices do not promote  
20    innovation, competition, or affordability. Nor do  
21    they move the needle improving health and health  
22    outcomes for people with MS. Instead, they are

1       utilized to protect profitable revenue streams far  
2       past the timeframes which manufacturers need to  
3       recoup investments and build profits to drive  
4       further innovation.

5               It is with this background in mind that  
6       we make the following recommendations. Applicants  
7       should be required to certify that the statements  
8       made to both FDA and USPTO are consistent when  
9       they are seeking regulatory approval for a new  
10      drug application. Lengthy patent protections or  
11      extended market exclusivity for minor tweaks to  
12      existing products should not be granted. Further,  
13      USPTO should end the use of terminal disclaimers  
14      to overcome obvious-type double patenting. Or  
15      require a binding admission within the terminal  
16      disclaimer that claims are not patentably distinct  
17      from previously granted claims to which there are  
18      obvious variations.

19             USPTO should help provide transparency  
20      by updating its centralized listing of PTE  
21      applications to include the terminal disclaimer  
22      language and/or all patents that are associated

1 with the original patent. Both the USPTO and the  
2 FDA should work collaboratively with the Federal  
3 Trade Commission to establish what actions do and  
4 do not constitute gaming of the system, and have  
5 those actions be publicly available. Examine the  
6 patentability of REMS programs and engage all  
7 stakeholders in meaningful dialogue including  
8 patients.

9 Relatedly, the USPTO should engage  
10 patient and patient advocacy groups as members of  
11 the Patent Office Public Advisory Committee. And  
12 both agencies should work closely with  
13 congressional leaders to assure they have the  
14 authorities and resources necessary to effectively  
15 engage in and act on their collaborative work.

16 Thank you for the opportunity to provide  
17 feedback and recommendations here today. The  
18 Society's full comment has been submitted to the  
19 docket and we look forward to working with you.

20 JUDGE HORNER: Great, thank you, Ms.  
21 Ritter, for being here today. For sharing the  
22 insights of patients and the perspective from

1 patients and for the recommendations that you've  
2 provided. I'll turn to the panelists and see if  
3 we have any questions from the panel.

4 JUDGE BONILLA: I had one question. One  
5 of your recommendations was that the Patent Office  
6 do away with the terminal disclaimers in relation  
7 to obviousness-type double patenting. Patents  
8 that are issued that have this terminal disclaimer  
9 they expire on the same day as the patent which  
10 they're doing the terminal disclaimer. Does that  
11 alleviate some of your concerns? Or are there  
12 additional concerns about the terminal disclaimer  
13 situations in patents that are worth sharing with  
14 us?

15 MS. RITTER: I'm sorry, it was a little  
16 mumbled in the middle. Can you repeat that?

17 JUDGE BONILLA: I apologize. It was the  
18 mask. I'm going to take it off. On patents that  
19 have the terminal disclaimer based on a patent  
20 that issued earlier, those patents expire on the  
21 same day.

22 MS. RITTER: Mm-hmm.

1 JUDGE BONILLA: I was just curious as to  
2 -- because you're suggesting to do away with  
3 terminal disclaimers, if you had additional  
4 concerns since the issue of when they would  
5 expire, they would be on the same day.

6 MS. RITTER: Right. I think our concern  
7 is when you have -- I think that would alleviate  
8 some of the concerns. I think that when you have  
9 -- our concern is when generic competition is  
10 looking for patents to challenge, often it is  
11 impossible to address the multiple patents that  
12 are associated with the product. We're looking  
13 really to end that practice because patients  
14 really look at what is the patent end date? When  
15 can I expect a generic to come on market when  
16 they're looking for affordability. Anything to  
17 improve that process and make that process seem  
18 more fair, and move more quickly, and within the  
19 intent of Hatch-Waxman would be an improvement  
20 that we would like to see.

21 JUDGE HORNER: I have a question  
22 following up on that. Does the listing of the

1 patents in the Orange Book help in that regard for  
2 companies to know which patents cover the  
3 products? You may have 20 patents on a product,  
4 but only a lesser number in the Orange Book  
5 listing.

6 MS. RITTER: Yes, I think that you  
7 highlighted one of the challenges. I think the  
8 challenge that we most see is looking at what  
9 patents are associated that kind of protect around  
10 the thicket. So, you may have some patents listed  
11 in the Orange Book, but the ones that are actually  
12 being used to kind of deter generic competition  
13 are not necessarily listed or are listed in other  
14 places. So, it's very hard to kind of keep track  
15 of what patents are actually being challenged and  
16 are providing the challenge to the system and in  
17 what status those are in.

18 JUDGE HORNER: One last question before  
19 we run out of time.

20 MS. RITTER: Yes.

21 JUDGE HORNER: On another recommendation  
22 you mentioned about using patients and patient

1 advocacy groups --

2 MS. RITTER: Mm-hmm.

3 JUDGE HORNER: -- to provide input. Has  
4 your organization been involved in similar  
5 advisory groups for other agencies? And how has  
6 that worked? And what sort of model has it  
7 followed?

8 MS. RITTER: Sure. And I'll try to be  
9 very quick because I know we're running out of  
10 time. The FDA has a patient panel that could  
11 actually serve as a good model for this. They  
12 routinely engage patients. There is a process by  
13 which the patients apply, have to be kind of  
14 vetted through the system, and sign on as I think  
15 they're contract government employees for that  
16 period of service. But we think that's a good  
17 model that the USPTO could utilize to look at  
18 this.

19 JUDGE HORNER: Great. Thank you very  
20 much.

21 MS. RITTER: Thank you.

22 JUDGE HORNER: And now if our conference



1 services folks can have our next speaker appear on  
2 the screen, Ms. Sneha Dave, from Generation  
3 Patient.

4 MS. DAVE: Yes. Can you all see me  
5 okay?

6 JUDGE HORNER: We can, yes, we can see  
7 you. Welcome. Welcome.

8 MS. DAVE: Amazing.

9 JUDGE HORNER: So --

10 MS. DAVE: Okay, great.

11 JUDGE HORNER: -- please go ahead and  
12 deliver your remarks and then we might have a few  
13 questions.

14 MS. DAVE: Great. So, my name is Sneha.  
15 I am 24 years old and I was diagnosed with a  
16 severe form of ulcerative colitis when I was six  
17 years. I created what is now Generation Patient  
18 around 10 years ago when I felt like there was not  
19 enough support for adolescents and young adults  
20 with chronic conditions.

21 Generation Patient is still entirely led  
22 by young adult patients and we focus on peer

1 support, higher education, and health policy.  
2 Over the last two years, we have done over 400  
3 peer support meetings and developed novel  
4 programming and advocacy related to higher ed  
5 avenues. But our work in health policy is  
6 extremely important to me because I have seen  
7 firsthand the disparities in our community that  
8 are often fueled by the high prescription drug  
9 costs that we need to survive.

10 Early on, we at Generation Patient made  
11 the decision to decline all funding from the  
12 pharmaceutical, insurance, hospital, or related  
13 healthcare industries to keep the integrity of our  
14 work. Through our only disease-specific  
15 programming, the Crohn's and Colitis Young Adults  
16 Network, we work to empower adolescents and young  
17 adults with inflammatory bowel diseases.

18 Humira is a medication that I was on for  
19 a number of years and one that is needed by many  
20 in our community. And it has been granted over  
21 166 patents and has delayed biosimilar entry until  
22 2023 in the United States. This is just one of

1 the many examples which illuminates and which is  
2 why it is so exciting to have this USPTO and FDA  
3 collaboration.

4 The following points that I make are  
5 going to be divided into sections based off what  
6 we feel like is most important to address. So,  
7 the first is to engage patient stakeholders.  
8 Patient stakeholders are critical, but often  
9 underrepresented at its equal stakeholders and  
10 policy and regulatory discussions. The USPTO and  
11 FDA must have accountability to those most  
12 impacted in all aspects of the collaboration.

13 We recommend the development of an  
14 independent public advisory committee, inclusive  
15 of patients who represent areas from chronic to  
16 rare diseases, different age groups, and more.  
17 This independent public advisory committee should  
18 play a critical role in advising on public  
19 dissemination of information, best practices for  
20 engaging public and patient stakeholders in ways  
21 in which this collaboration could be even more  
22 patient centered.

1           We commend that the FDA already has a  
2   variety of existing patient engagement  
3   opportunities of which I am a part of. Rather  
4   than just also having patients serve on separate  
5   patient councils, we encourage the integration of  
6   patients in all core activities of this  
7   collaboration. We also wish to encourage the  
8   foremost engagement of individuals in  
9   organizations that are independent of  
10   pharmaceutical industry funding. Further, as part  
11   of an advisory council, we uphold that patients  
12   must be compensated for their time and experience  
13   to ensure that there is an equitable  
14   representation of who can provide this insight.

15           The second point is this idea of  
16   value-based patents. Before a patent extension is  
17   granted, it is important to understand what  
18   benefit the drug actually has on patients. Does a  
19   secondary patent meaningfully increase the  
20   clinical benefit and post a transformative impact  
21   on patient quality of life?

22           Modifying a drug without a meaningful

1 impact on the utility proves unnecessary in  
2 improving patient lives. It should not warrant a  
3 new patent that allows drug manufacturers to  
4 continue escalating the cost of lifesaving drugs  
5 for patients. As patients, we need novel  
6 medications, not the ones we have already tried  
7 and which have not worked for us.

8           When we reward pharmaceutical companies  
9 with new patents on old drugs, we remove the  
10 financial incentive (audio skip) establish  
11 channels for sharing information about an  
12 applicant. Patent examiners should have access to  
13 a wide array of information when conducting prior  
14 art searches such as including updated information  
15 from the Purple and Orange Books, FDA decisions,  
16 and scientific information.

17           We also recommend that when considering  
18 these additional patents, sponsors can be held  
19 accountable to share robust evidence, diversity in  
20 trials, and adequate documentation of safety data  
21 earlier on.

22           The last point is that this

1 collaboration is a unique opportunity to place an  
2 emphasis on pediatric adolescent and young adult  
3 patient populations. These are populations that  
4 have been historically left behind within clinical  
5 research. We encourage novel ways of thinking to  
6 incentivize pharmaceutical companies to truly  
7 innovate to develop drugs for pediatric  
8 populations.

9           Further, there must be better incentives  
10 for evidence generation earlier on, rather than  
11 nearing the end of an initially granted patent.  
12 For example, a study showed that approximately one  
13 in 10 pediatric trials ended early and that the  
14 results of the majority of these had not been  
15 published even three years later. We feel that  
16 the incentive is low for actually completing  
17 pediatric studies. Rather, it feels like there is  
18 simple encouragement of earlier pediatric research  
19 without the actual timely completion.

20           We suggest a sense of urgency for  
21 creating a collaborative system in which there is  
22 a true incentive to bring pediatric-approved

1       therapies to market rather than creating  
2       opportunities to delay generic and biosimilar  
3       competition.

4               We also wish to note that when the  
5       patent system is misused and when me-too drugs are  
6       created, our demographic of young people with  
7       chronic conditions are disproportionately  
8       affected. We run out of treatment options quickly  
9       and we have a lifetime ahead of us. We need novel  
10      innovation fairly priced.

11             We welcome continuing to partner with  
12      the USPTO and FDA to include patients at the  
13      forefront of all actions taken through this  
14      important collaboration. Thank you.

15             JUDGE HORNER: Thank you very much, Ms.  
16      Dave, for your work. It's impressive what you're  
17      doing with your group. I did want to ask on the  
18      idea that you mentioned, the suggestion you  
19      mentioned of this independent public advisory  
20      committee. Have you been involved or has  
21      Generation Patient been involved in those kinds of  
22      groups before? And again, what kind of model do

1     you think works best to get patient input and  
2     patient involvement?

3             MS. DAVE:  Yes.  So, we've been on a  
4     number of -- or I have represented and some of our  
5     community members have represented Generation  
6     Patient on the FDA Patient Engagement  
7     Collaborative and a couple of other like  
8     opportunities through ICER and some other sorts of  
9     non-profits and other organizations.  And we  
10    really feel like a lot of times the patients that  
11    are included in these discussions are not the  
12    patients that, you know, reflect our community on  
13    a grassroots level.  And so, I think a huge  
14    problem is that there is often not opportunities  
15    for compensation for patient time.

16            I think also a lot of times with  
17    agencies, there's a lack of plain language to  
18    really ensure that all patients can understand  
19    information in an accessible manner.  I mean, even  
20    for us as a non-profit group, it takes us a lot of  
21    time to look into information.  And we ask people  
22    so many questions because a lot of this language



1 is not done in like plain language concepts. And  
2 so, we really believe that an advisory council  
3 like this or at least adding patients to existing  
4 ones could increase opportunities for  
5 dissemination of a lot of this material.

6 JUDGE HORNER: Great, thank you. Any  
7 questions from our other panelists?

8 JUDGE BONILLA: I have one question.  
9 And first, I wanted to start out by saying how  
10 incredibly impressive it is that you are doing  
11 this at such a young age and sort of making  
12 lemonade out of lemons of your personal situation.  
13 So, thank you so much for doing that because I  
14 think hearing from you, especially on the  
15 pediatric side, I think is so valuable for us to  
16 hear.

17 I did have a question. And one of your  
18 recommendations had to do with patent term  
19 extension and, you know, taking a look what  
20 benefit it actually has for patients. I know some  
21 of the things that we hear on some of these what  
22 they're called secondary patents is they actually

1       are pretty significant improvements of the  
2       existing -- the way the existing, you know,  
3       medicine is, you know, for example, could be, you  
4       know, lowering side effects, or stability, or, you  
5       know, things like that. Do you consider those to  
6       be sufficient to be taken into account even when  
7       it's a secondary patent on the same drug?

8               MS. DAVE: Yeah, again, I think it  
9       depends on what the actual patent is for. So, if  
10      it's something like side effects, I think that's  
11      incredibly important. But we've also seen other  
12      things like very basic things that may not  
13      actually warrant a patent extension and may not  
14      actually have a benefit to where it's worth to  
15      have an additional, you know, couple of years or  
16      however long it is. So, I think that's where it's  
17      also really important to have patients involved in  
18      determining some of these like what is the value  
19      of the actual added benefit, so.

20             JUDGE HORNER: Other questions? I'll  
21      just have one more of a comment but just for  
22      awareness. So, one of the suggestions that you

1       made dealt with what patent examiners have access  
2       to in terms of searching. And I will say that  
3       we've done some cross-training already on patent  
4       examiner searching with the FDA. We've done  
5       training and looked in depth at what resources  
6       examiners already have.

7               And they do have quite a number of  
8       resources outside the USPTO patent database. They  
9       also search Orange Book and Purple Book  
10      information. They have access to public  
11      information available through FDA databases. So,  
12      their searches are very comprehensive but we're  
13      still working together to look and see if there's  
14      any other information that they don't have ready  
15      access to or aren't familiar with that they might  
16      want to consider searching. So, we'll certainly  
17      keep looking at that issue as we move forward.

18             MS. DAVE: Great, thank you so much.

19             JUDGE HORNER: Thank you for being here  
20      today, and for speaking, and for providing us with  
21      a great perspective from a patient advocacy  
22      viewpoint. So, thank you.

1 MS. DAVE: Thank you.

2 JUDGE HORNER: Okay. That concludes  
3 Session 1. We're going to move to Session 2. And  
4 we have one speaker for Session 2, Mr. Kevin Wren  
5 from TlInternational. So, if we have Mr. Wren  
6 already available online, we can go ahead. And as  
7 we're waiting to get him up on the screen, we'll  
8 have our panelists come and get seated. Dan, you  
9 can sit right here. Dan Kolker and Bethany,  
10 please. Thank you.

11 I'll have the panel do introductions in  
12 just a moment but I want to make sure Mr. Wren is  
13 connected first. So, we'll give him just a  
14 moment.

15 MR. WREN: Thank you.

16 JUDGE HORNER: Yeah, there you are.  
17 Hello, Mr. Wren.

18 MR. WREN: Hello.

19 JUDGE HORNER: We're going to have our  
20 -- hopefully, you can see our panel and we're  
21 going to have them introduce themselves and then  
22 you can deliver your remarks.

1 MR. WREN: Thank you.

2 MS. HURWITZ: Good morning. I'm Zahava  
3 Hurwitz, the Director of the Policy Engagement and  
4 Coordination Staff in the Office of Policy,  
5 Legislation, and International Affairs in the  
6 Commissioner's office at FDA.

7 MR. RITTERBECK: Good morning, Mr. Wren.  
8 My name is Dan Ritterbeck. I'm a regulatory  
9 counsel in CDER's Office of Regulatory Policy at  
10 the FDA.

11 MR. SULLIVAN: Good morning. I'm Dan  
12 Sullivan. I'm with the USPTO. I am Director of  
13 Technology Center 1600 where we do examination of  
14 most of the pharmaceutical inventions.

15 JUDGE HORNER: And, Mr. Wren, I'm Linda  
16 Horner. I'm an Administrative Patent Judge at the  
17 Patent Trial and Appeal Board at the USPTO.

18 MR. KOLKER: Good morning, Mr. Wren. My  
19 name Dan Kolker. I'm a supervisory patent  
20 examiner. So, I have direct oversight of 17  
21 patent examiners in the antibody and immunology  
22 area in the USPTO.

1 MS. BARHAM: Good morning. I'm Bethany  
2 Barham. I'm a supervisor patent examiner in Art  
3 Unit 1611, which we examine small molecules,  
4 cosmetics, as well as drug formulations.

5 JUDGE HORNER: Great. And that's our  
6 panel. And, Mr. Wren, you're welcome to deliver  
7 your remarks.

8 MR. WREN: Thank you. My name is Kevin  
9 Wren and I was diagnosed with diabetes over 20  
10 years ago. Over that time, my insulin  
11 prescription has remained relatively unchanged as  
12 new monitoring and delivery technologies have  
13 emerged. I live in Sacramento, California and I  
14 advocate with Insulin for All because no one  
15 should have to ration the insulin that they need  
16 to survive or the best treatments and technologies  
17 available. My colleagues Shaina Kasper and  
18 Emmabella Rudd will show more later about who we  
19 are and the work that we do.

20 Life with diabetes is complicated but at  
21 T1International, we believe that access to vital  
22 insulin, diabetes supplies, and medical care

1       should not be. I am grateful to have the latest  
2       insulin pumps and continuous glucose monitoring  
3       technologies and insulins, but I question whether  
4       the patent system as it exists today helps or  
5       hinders the innovation needed to get these  
6       technologies into the hands of patients.

7               The patients on these drugs and  
8       technologies need technology to protect their  
9       innovation are essential. My continuous glucose  
10      monitor, the Dexcom G6, reads my blood sugar  
11      levels every five minutes and gives me alarms when  
12      it is too high, too low, and going up or down too  
13      fast. I can access the readings on my phone and  
14      they connect to my insulin pump. However, these  
15      technologies are not available to everyone. I  
16      only have access to these new innovations because  
17      I live in poverty and I am able to access Medicare  
18      and Medicaid.

19             These are less widely used by the many  
20      people and Black, Indigenous, and People of Color  
21      who earn too much to qualify for Medicaid but too  
22      little to afford it. I am testifying today

1     because I have experienced rationing insulin and  
2     supplies and I believe that no one should have to  
3     do that. We should have access to vital  
4     medicines, care, and supplies due to where they  
5     live or what they do or how much they earn.

6             And because of manufacturing and patent  
7     manipulation and exploitation, combined with the  
8     lack of time and training on what is innovative,  
9     too many patients -- too many patents are being  
10    awarded for things that are not new, leading to  
11    rationing and serious health outcomes. I think  
12    that three things can be done today to improve  
13    training: More time, more training, and patient  
14    consultation.

15            First, patent examiners need more time  
16    for more examination. It may only take several  
17    years from filing a patent application for an  
18    applicant to receive a final patentability  
19    decision from the patent office. However, on  
20    average, an examiner spends only 19 hours  
21    reviewing an application. This can include a lot  
22    of different important and detailed work including



1 reading the patent application, searching for  
2 prior art, reading the prior art, and identifying  
3 the most pertinent references, comparing the prior  
4 art with the patent application, writing a  
5 rejection, responding to the patent applicant's  
6 arguments, and often conducting an interview with  
7 the applicant's attorney. That's a lot to do in  
8 not much time. Patent examiners need more time.

9 Second, patent examiners need more  
10 training and resources for patent examiners.  
11 Training should be inclusive of both FDA reviewers  
12 and PTO examiners so both parties have consistent  
13 understanding of products under review.

14 Finally, patients need to be more  
15 involved in the process and patients should be  
16 involved in the training. As patients, we are the  
17 experts in living with diabetes and these  
18 conditions. And we should have the opportunity to  
19 consult and offer our expertise on technologies  
20 and innovations, including the state of art in  
21 diabetes care. Examiners listening only to  
22 pharma's lawyers everyday about what they think

1 the state of the art is, is leading to bias.  
2 Having only training from pharma is leading to  
3 bias.

4 For too long, drug makers like insulin  
5 manufacturers Eli Lilly, Novo Nordisk, and Sanofi  
6 managed to manipulate the patent process and the  
7 lack of time allocated for the reviewing process  
8 allowing them to evergreen patents and exploit  
9 flaws in the system. We, the patients, see the  
10 true impact of these innovations, yet we are left  
11 out of the conversation and the process that  
12 impacts our health and the lives on a constant  
13 basis.

14 We should be included and addressed as  
15 part of the patent examination process for drugs.  
16 We can see the blind spots and can help ensure  
17 that a patent fulfills its promise to help us  
18 manage our chronic conditions. This hearing  
19 underscores the importance of independent patient  
20 and consumer group perspectives.

21 I am able to speak remotely due to ACA  
22 accommodations because I am a patient. However,

1 the PTO's decision to prohibit remote speaking  
2 silences a lot of voices, including members of the  
3 T1International's Families United for Affordable  
4 Insulin who didn't feel welcome to come despite  
5 having lost loved ones due to insulin rationing  
6 due to cost.

7           The technologies that I have should be  
8 accessible to everyone. Racial healthcare  
9 disparities is very persistent in diabetes care.  
10 A study recently published in Diabetes Technology  
11 and Therapeutics found that even though use of  
12 insulin pumps for type 1 diabetes has grown in the  
13 past two decades, there was no improvements in  
14 racial gaps.

15           In order to fulfill its promise of  
16 equity and inclusion, the FDA must prioritize  
17 patient voices within the review of a patent. To  
18 that end, the FDA must give space for Black,  
19 Indigenous, and People of Color, as well as those  
20 in the LGBTQ+ community, in order to fully  
21 understand the impact of patents -- of patents on  
22 marginalized groups.

1                   PTO and FDA include patients, patient  
2           groups, and patient coalitions because we live  
3           with the conditions consuming these drugs.  
4           Patients must be at the table and our voices must  
5           be heard amid the examination process. If the  
6           process is to be equitable, then it must include  
7           those who are most affected. The disproportionate  
8           lack of access among BIPOC communities to emerging  
9           technologies, like my continuous glucose monitor  
10          and my insulin pump, means the system is racist.  
11          If we are not given a voice within the process,  
12          then you are allowing inequities to persist and  
13          fester. If we are not given reasonable  
14          accommodation to be part of the process, the  
15          system is ableist.

16                 Only by centering the examination  
17          processes for drug patents on patients can the FDA  
18          fulfill its commitment to protect public health.  
19          New drugs and technologies can be lifelines for  
20          those struggling and we must include patients  
21          within the examination process because this is  
22          truly life, death, and good health. Thank you.

1 JUDGE HORNER: Mr. Wren, thank you for  
2 being here today for taking the time to prepare  
3 these remarks and share your story and your  
4 perspective, and we value your input. I'm going  
5 to turn to our panelists to see if we have any  
6 questions from the panel.

7 MR. KOLKER: So, one thing you mentioned  
8 was the amount of time it takes for a patent  
9 application to be reviewed and a patent applicant  
10 to get a final decision, as well as the relatively  
11 small amount of time, you cited 19 hours that an  
12 examiner has to look at a patent application. And  
13 I feel like this is a tension that the USPTO is  
14 always dealing with that we want to give examiners  
15 time and yet we want to get decisions to  
16 applicants more quickly. And so, what would be  
17 your recommendation for where we should swing  
18 between looking at more applications versus  
19 spending more time per application?

20 MR. WREN: Yeah, I think the system is  
21 geared towards the patent applicants not the  
22 patients that are receiving the care. So, I think

1 in trying to move efficiently, you ignored simple  
2 aspect of the process, and that's patient voices.  
3 I think, I mean, just given the sheer number of  
4 patents that are being reviewed, it makes sense  
5 that it should be like a just like a factory model  
6 where you're just getting it through.

7 But some of these have real dire impacts  
8 on people's health. And I think 19 hours is not  
9 nearly enough. You ask anyone who has any idea of  
10 what a patent application might be, we need way  
11 more time to review these things and include  
12 patient voices. I don't have a set number of time  
13 that you should increase it by, but I think the  
14 process itself should be reexamined and completely  
15 redone.

16 MR. KOLKER: Thank you. And then I'd  
17 like just to make a comment as well just so that  
18 you and your community are aware of it. You said  
19 that there needs to be more voices and that we  
20 need to understand the patient's perspective. And  
21 I'll just point out that there is a mechanism  
22 already in place called a third-party submission,

1       which allows someone to submit things that they  
2       think might be prior art. And I'm not going to  
3       get into the details of it, but it's called a  
4       USPTO third-party submission. And that does exist  
5       already and it's open to members of the public.

6               MR. WREN: Thank you.

7               MR. SULLIVAN: So, yeah, thanks for your  
8       comments. So, there was some earlier discussion  
9       about, you know, patient group advisory committees  
10      as a means for giving, you know, patients access  
11      to the agencies. And I just wanted to know if,  
12      you know, you're involved in those or aware of  
13      those, and is that something that you think  
14      addresses the concerns that you have about access  
15      to the agencies? Or are there other ways that you  
16      think that patients should be -- or other ways  
17      that patients could have a voice in what the  
18      agencies are doing?

19              MR. WREN: Yeah. I think Sneha said it  
20      pretty well. But I mean, just an example from my  
21      own life. In Washington State we have a Total  
22      Cost of Insulin Work Group where we looked at the

1 total cost of insulin and why it's so expensive  
2 and ways to make it more affordable. And from my  
3 testimony, we were able to establish five  
4 positions for members of the public who have the  
5 disease to balance voices from pharma, the  
6 hospital industry. I mean, without my testimony  
7 and without us like fighting for it, we wouldn't  
8 have gotten a seat at the table.

9           So, I think too often we're having to  
10 fight for these seats and they should be made  
11 available just as like a basic concern. I mean,  
12 this should be built in. We shouldn't have to  
13 have like fight and struggle just to get our  
14 voices heard. I mean, just appearing today in  
15 this room like I had to wake up at 7:00 a.m. I  
16 had to do a whole of stuff to get prepared. And a  
17 lot of patients who are suffering with chronic  
18 conditions, don't have that kind of time or  
19 resources. So, I think you say the process is  
20 open, but it needs to be made way more open.

21           JUDGE HORNER: Any other questions from  
22 panelists? Dan?



1                   MR. RITTERBECK: Yeah, thanks again for  
2                   your comments. I just wanted to make a quick  
3                   distinction that I think is important. There were  
4                   a couple statements in your comments that seemed  
5                   to suggest that FDA is involved in the examination  
6                   of patents and I just want to make sure that you  
7                   and your community are aware that FDA does not  
8                   examine patents. We're tasked with reviewing drug  
9                   applications. And so, I just wanted to, you know,  
10                  make sure we were clear about that. That's all.

11                 MR. WREN: Sorry for that misconception.

12                 MR. RITTERBECK: No, no, no problem. I  
13                 just wanted to make that distinction, thanks.

14                 MR. WREN: Thank you.

15                 JUDGE HORNER: And, Mr. Wren, I'm  
16                 intrigued by the idea of examiners having an  
17                 opportunity to hear from patients about state of  
18                 the art because you're the ones using the  
19                 products. And so, you know, we do have a program  
20                 at the USPTO that allows examiners to make site  
21                 visits or to get training about state of the art  
22                 from industry. And I think, you know, that's a

1 suggestion we'll take back and think about is  
2 whether that could be expanded to include patient  
3 groups so that examiners get that perspective as  
4 well. So, thank you again.

5 MR. WREN: Thank you so much.

6 JUDGE HORNER: Thank you for your time.  
7 This concludes Session 2. We're going to take a  
8 break. We'll reconvene at 11:30 for Session 3.

9 (Recess)

10 JUDGE HORNER: So, if everyone could  
11 take their seats. All right, welcome back. So,  
12 we have a full Session 3. We have six speakers.  
13 Our fourth speaker will be virtual. So, we'll  
14 take a little break from the room and see our  
15 virtual speaker. Our first speaker is Professor  
16 Robin Feldman from the University of California  
17 Hastings College of the Law. Professor Feldman,  
18 you may deliver your remarks.

19 PROF. FELDMAN: Let's see. There we go.  
20 Thank you. It's an honor to be here but I'm not  
21 sure that my mic is working. Thank you. Ah,  
22 that's so much better. Okay. Thank you. It's an

1 honor to be here.

2 A few years ago, my coauthors and I  
3 published a piece in Nature Biotechnology focusing  
4 on patents for a cancer drug that unfortunately  
5 protect excessive doses of the drug. Those patents  
6 thereby encouraged treatment at unnecessarily high  
7 doses. Discussing these and other concerns, we  
8 suggested greater coordination between the FDA and  
9 the PTO to ensure that each agency would know what  
10 the other is doing and to avoid the possibility  
11 that applicants could say different things to each  
12 agency. I am, therefore, heartened to see all of  
13 the efforts going on today.

14 I do want to be clear that I believe the  
15 problem goes beyond the potential for directly  
16 inconsistent statements because patent examiners  
17 normally are not clinicians. That is, they are  
18 not physicians or pharmacists. And they're also  
19 not normally pharmaceutical researchers. Input  
20 from the FDA can fill that knowledge gap helping  
21 patent examiners determine whether a  
22 pharmaceutical application represents a true

1 innovation or rather something that is obvious to  
2 physicians or obvious to the FDA itself. It's  
3 where to look in the vast amount of information  
4 that's out there.

5           Such communications can also help the  
6 PTO determine whether the claims are based merely  
7 on routine optimization or even an action  
8 requested by the FDA. With that in mind, I'd like  
9 to offer a few examples of reasons why lines of  
10 communications could be helpful.

11           So, first, a company shouldn't be able  
12 to tell the FDA this drug product is essentially  
13 the same as what we have out there. So, no  
14 further testing that's needed. And then go to the  
15 FDA -- go to the PTO and say the product is  
16 entirely new. Either it's new, it's the same, or  
17 it's not. One or the other. It can't be both new  
18 and the same at the same time.

19           Similarly, if the FDA is not convinced  
20 by the clinical data, then that data shouldn't be  
21 the basis for a patent claim. Suppose the FDA  
22 doesn't allow a comparative clinical study in the

1 product information. In other words, the company  
2 won't be allowed to say our drug causes fewer  
3 headaches than what is currently on the market.  
4 In that case, the company shouldn't be able to get  
5 a patent by claiming that the drug causes fewer  
6 headaches.

7           From another perspective, if the FDA is  
8 telling a drug company to take an action or  
9 investigate an aspect of the drug, the company  
10 shouldn't be able to patent the results of that  
11 investigation. If the FDA directs your action,  
12 then it isn't novel and it was certainly obvious  
13 to try. This is not to impute nefarious motives  
14 to pharmaceutical companies. Rather, it is  
15 unfortunately too easy and perhaps just human  
16 nature for companies to emphasize for the FDA  
17 little is new, nothing to worry about, no data  
18 needed. And yet, to emphasize for the PTO that  
19 the drug product is wonderfully different and  
20 innovative.

21           Applicants are speaking to their own  
22 interests at each agency. But society has a

1       larger interest and that's to get to the truth of  
2       the matter and make sure each agency has the full  
3       picture. I'd like to suggest some steps that  
4       could help ensure consistency.

5               First, consider specifying that if an  
6       applicant makes a representation to the FDA and  
7       the issue is relevant to a patent application, the  
8       applicant should disclose to the PTO the same data  
9       analysis and conclusions as those submitted to the  
10      FDA.

11             Second, establish more formal  
12      communication inputs for the agencies regarding  
13      applications. One could begin by communicating  
14      about a smaller subset of patent applications such  
15      as those that include method of use or formulation  
16      claims. A group of patents more likely to be  
17      subject to litigation. Smaller steps like these  
18      can help work out the problems in the system and  
19      the effort could expand to other types of  
20      secondary or tertiary patent applications.

21             A key time for patent examiners to avail  
22      themselves of experts at the FDA would be when

1 reviewing applicants' responses to patent office  
2 rejections, particularly if the applicant responds  
3 with affidavits attesting to specific clinical or  
4 pharmacological findings. In this context, the  
5 PTO could obtain information from FDA employees  
6 that may support examiner findings and could also  
7 access the documents submitted to the FDA. Again,  
8 the issue isn't the vast amount of information  
9 that's out there sometimes. Sometimes the  
10 innovation isn't out there. But it's a question  
11 of knowing where to look and what matters to those  
12 who are on the ground in the field.

13           It's possible that the relevant  
14 information should not yet be released to the  
15 public. Consider information existing prior to  
16 drug approvals, such as a request for permission  
17 to test the drug in humans. If so, perhaps there  
18 could be a separate file wrapper in which the  
19 information remains sealed until the appropriate  
20 time.

21           I am concerned, however, about some of  
22 the things that are happening in the context of

1 confidential information just in general. Trade  
2 secrets, claiming trade secrets, a broader  
3 category than confidential information, has become  
4 like a magic wand. People waive it and everyone  
5 backs off. Trade secrets do play an important  
6 role in the pharmaceutical industry. However,  
7 there is quite simply considerable overreach with  
8 trade secrets at the moment. Federal trade secret  
9 law does not preempt the Patent Act, nor does it  
10 preempt the Hatch-Waxman Act or the Biosimilars  
11 Act. State trade secret laws don't preempt any of  
12 those either. So, patent and regulatory  
13 disclosure processes should not simply fold in the  
14 face of trade secret claims. They need to be  
15 looked at more carefully.

16 I would close by saying that thanks to  
17 the work of PTO directors and staff in recent  
18 administrations, both Republican and Democrat, we  
19 now have enhanced mechanisms for the PTO to  
20 receive advice and information from counterparts  
21 in foreign countries and from industry. I believe  
22 it would be helpful for the PTO to also enjoy the



1 expertise of its own sister agency right next  
2 door. Thank you very much.

3 JUDGE HORNER: Thank you, Professor  
4 Feldman. I'm going to open it up for the panel.  
5 And we'll just start down on this end if you have  
6 any questions for Professor Feldman?

7 MR. RITTERBECK: Hi, Professor. I had a  
8 question for you. You had mentioned the -- you  
9 coauthored a published piece about a patent that  
10 protected excessive doses of a particular  
11 treatment and you said that that encouraged  
12 treatment with those excessive doses. I'm just  
13 curious, has it been your experience that  
14 healthcare providers or patients are relying on  
15 patents in order to inform treatment decisions?

16 PROF. FELDMAN: No, patents don't  
17 inform, but they do inform what product gets to  
18 market. And that matters for what's accessible,  
19 what's available to the parties. So, in that case  
20 that you're referring to, the FDA specifically  
21 encouraged and noted its concern about the  
22 excessive dose. Encouraged the folks to test it

1       at lower doses, to look for that product. That's  
2       not going to happen because lower doses weren't  
3       patentable.

4               In the case you're describing, the  
5       companies picked the one tiny slice that was  
6       available among all of the patent rights that  
7       existed and other types of information of prior  
8       art to patent. That was helpful for getting a  
9       patent. It's not necessarily helpful for  
10      patients.

11             MR. RITTERBECK: Thank you.

12             JUDGE HORNER: Any questions from this  
13      end of the table?

14             MS. FERRITER: I'll ask a question. You  
15      mentioned that comparative claims that are not  
16      substantiated before FDA should not be patented.  
17      On what statutory basis would PTO be able to rely  
18      on to reject such type of claim? And then since  
19      that FDA submission would typically be well after  
20      a patent application had already been on file and  
21      likely examined, how would the applicant then be  
22      able to address that issue?

1                   PROF. FELDMAN: So, let me see if I can  
2 address the second one first then I'll go back to  
3 the first. And that is if you think about a  
4 biosimilar application, yes, there's a great deal  
5 -- and I'm talking about applications in either  
6 agency -- yes, there's a great of time that  
7 passes. But there are also obligations to update  
8 information if there are changes made to the drug.  
9 So, you have information that is coming into the  
10 PTO.

11                   There is certain -- I'm sorry -- that's  
12 coming into the FDA. There is certainly an issue  
13 in which the FDA gets its information well after  
14 the PTO gets its information, which I think is  
15 what you are talking about. However, if you have  
16 proper disclosure of information by both agencies  
17 along the way, and you have file wrappers when  
18 it's appropriate for that information to become  
19 public, and you have the FDA disclosing the  
20 information at the time that it becomes public,  
21 then it becomes possible for others to challenge  
22 the patent and to understand and to put the pieces

1       together. So, I think that's a piece.

2                You are right that I think there's a  
3       problem with how early we grant rights in some of  
4       these areas. And I think that is something worth  
5       looking at. But it's not the subject of today's  
6       hearing.

7                The first you asked -- the first  
8       question though you asked about is what is the  
9       statutory basis. So, for any -- and I -- you  
10      know, you and I can talk about the, you know, the  
11      five elements of patentability. But I think what  
12      you're saying is that it's difficult to rebut a  
13      claim particularly a claim that's made in an  
14      affidavit by a patent applicant. But a patent  
15      examiner can look at any information that exists  
16      out there for making a determination of whether  
17      something is novel or would be obvious to those in  
18      the field or a claim that's simply doesn't have  
19      validity.

20               That's why in an office objection, one  
21      can challenge the question of the assertions that  
22      are made by the applicant. The applicant in that

1 case may come back and just put an affidavit in.  
2 But it can be useful if an agency that actually  
3 knows something can say either that affidavit is  
4 problematic based on what the applicant has told  
5 us. That is something that can be useful. I  
6 agree with you that timing's a problem in this  
7 area.

8 JUDGE HORNER: Thank you, Professor  
9 Feldman. Unfortunately, we're out of time. I'm  
10 sure our panelists have more questions. But for  
11 the sake of keeping this moving and keeping to our  
12 time allotted, we're going to move ahead to our  
13 next speaker.

14 PROF. FELDMAN: Thank you. And I would  
15 welcome other questions if folks want to  
16 follow-up. I also note that with my apologies  
17 your staff was kind enough to give me the first  
18 slot here because I do have a plane to catch. So,  
19 I will disappear from the panel at some time, but  
20 with great respect to those who are speaking after  
21 me. Thank you so much.

22 JUDGE HORNER: Thank you. Our next

1 speaker is Mr. Tahir Amin from the Initiative for  
2 Medicines, Access, and Knowledge, I-MAK.

3 MR. AMIN: Thank you, Linda. And thanks  
4 to the USPTO and FDA for hosting this listening  
5 session and for allowing me to make some remarks.

6 My comments are specific to the FDA  
7 guidance on polymorphic forms and the patenting  
8 practices around them. In 2000, the FDA published  
9 a guidance document, which is available in my  
10 comments. And in that guidance the FDA sets out  
11 how polymorphic forms should be monitored and  
12 controlled by companies for new drug substances  
13 and products.

14 As the guideline states, some new drug  
15 substances exist in different crystalline forms  
16 that differ in their physical properties. In  
17 cases where differences exist that are being shown  
18 to affect drug product performance, such as  
19 bioavailability, stability, then the appropriate  
20 solid state should be specified. The guidance  
21 then provides how physiochemical measurements can  
22 be obtained and these are various sort of

1 techniques, which are commonly practiced in the  
2 industry, such as hot-stage microscopy, solid  
3 state IP, x- ray powder diffraction, and so on. I  
4 won't reveal the whole list. But these are common  
5 practices that the industry uses.

6           There's also in the guidance a decision  
7 tree, which sets out how drug applicants need to  
8 go about testing for these polymorphs. And  
9 related to that there is what we call the  
10 investigation of a new drug application. Now,  
11 current federal law requires that a drug be the  
12 subject of an approved marketing application  
13 before it is transported or distributed across  
14 state lines. Because a sponsor will probably want  
15 to ship an investigational drug to clinical  
16 investigators in many states, it must seek an  
17 exemption from that legal requirement. And the  
18 IND is the means through which the sponsor will do  
19 that.

20           Now, it's important to recognize the IND  
21 application must contain information in three  
22 broad areas: Manufacturing information pertaining

1 to the composition, stability, which is very  
2 relevant to polymorphs, and controls used for  
3 manufacturing the drug substance and the drug  
4 product. This information is assessed to ensure  
5 the company can adequately produce and supply  
6 consistent batches of the drug.

7 So, accordingly, the FDA requires  
8 polymorphic screen data to be submitted by a  
9 company seeking to bring a new product to market  
10 in its original IND application before Phase 1  
11 clinical trials. Therefore, polymorphic data on  
12 the new drug can be available to the FDA anywhere  
13 between three to six years before the drug is  
14 finally approved.

15 So, how does that affect polymorphic  
16 patenting and practice? Despite the FDA guidance  
17 for routine testing for polymorphs, I refer to  
18 that decision tree, and that such information is  
19 provided to the FDA as early as the IND  
20 application stage where is applicable, our review  
21 of patent filings for polymorphic forms for a  
22 number of drugs shows that they are often filed by



1 companies considerably later. So, while it is  
2 recognized that information on polymorphs are  
3 provided through an IND to the FDA is treated as  
4 confidential information, it appears companies are  
5 using this confidentiality to delay the filing of  
6 the patents on these polymorphs in order to  
7 stretch out their patent protection for as long as  
8 possible.

9 In essence, companies are being allowed  
10 to protect the polymorphic data they provide to  
11 the FDA as a trade secret until they conveniently  
12 decide that the relevant polymorph patents for the  
13 purpose of meeting the listing requirements on the  
14 U.S. FDA Orange Book, as required by Hatch-Waxman,  
15 or simply for defensive litigation purposes.

16 I just want to illustrate this with the  
17 example of the drug Revlimid, which is a cancer  
18 drug to treat multiple myeloma. The main compound  
19 patent of the drug lenalidomide, which is what  
20 constitutes Revlimid as developed by Celgene, is  
21 U.S. Patent 5635517. It was filed on the 24th of  
22 July in 1995 and expired on the 4th of October

1       2019. According to a source at the Mayo Clinic  
2       who worked on the preclinical trials for  
3       lenalidomide, it is understood that the drug was  
4       under clinical investigation in 1999 and 2000,  
5       which would have required an IND at the submission  
6       of relevant polymorph data and the submission of  
7       relevant polymorph data to the FDA as I've  
8       described.

9               However, Celgene did not submit its  
10       patent application for the polymorphic form of  
11       lenalidomide until the 3rd of September 2004,  
12       which is U.S. Patent 7465800, which expires on 27  
13       of April 2027. That's roughly four to five years  
14       after clinical investigation commenced and adding  
15       another eight years of patent protection be on the  
16       main compound patent.

17              Furthermore, between 2008 and 2020,  
18       Celgene then applied for several other patents  
19       covering polymorphic forms of lenalidomide. Many  
20       of them were divisionals but also -- so, it didn't  
21       extend the actual expiry of the patent, it didn't  
22       extend the protection of the patent -- but also,

1       there was completely new patent application for a  
2       different polymorph, U.S. 9808450, which was filed  
3       on the 25th of March 2014, expiring 25th of March  
4       2034.

5               Now, this patent data is available now  
6       at Drug Patent Book, which you'll probably hear a  
7       lot about today where people believe it's  
8       misleading, but I think it's important to  
9       recognize the universe of patents that you see on  
10      the Orange Book is not the universe of patents  
11      that corporations actually apply for and use in  
12      different various ways.

13             So, Celgene has entered into settlements  
14      with a handful of companies, which only allows for  
15      limited generic volume launch. So, only after  
16      2026 will the U.S. market see full unfettered  
17      competition, and that's because of these polymorph  
18      patents that they've delayed deliberately.

19             So, given the FDA guidelines on  
20      polymorphic screening and the routine testing  
21      that's required, I've got a couple of quick  
22      recommendations. I think first of all, the courts

1 currently see polymorphs as unpredictable, despite  
2 the routine testing. However, given polymorphs  
3 are inherent in the original compound and the FDA  
4 requires companies to find them as a matter of  
5 experimentation for the purpose of marketing  
6 approval, shouldn't it be the case that the USPTO  
7 revise its examination practice on polymorphs as  
8 being prima facie obvious?

9           Secondly, where companies are filing  
10 patents for other polymorphic versions much later  
11 than the first polymorph patent, even if it's a  
12 continuation or divisional, that does not extend  
13 the expiry of the patent and claiming surprising  
14 or unexpected advantages, such as stability, flow,  
15 or bulk density, these patents should be refused  
16 if the FDA had knowledge of these other forms at  
17 the time of the IND.

18           And finally, alternatively, and without  
19 prejudice to the recommendations above, once a  
20 company has submitted a polymorph screening to the  
21 FDA as part of its IND, it should have 30 days to  
22 file its patent applications for all polymorphs

1 identified to the USPTO. Failure to meet that  
2 requirement means the USPTO should refuse the  
3 application because otherwise they're using it to  
4 deliberately extend the patent. Thank you.

5 JUDGE HORNER: Thank you. I'm going to  
6 start at the other end of the table this time and  
7 see if we have any questions on this side.

8 MS. FERRITER: Sure. Thank you very  
9 much for your having made the written comments and  
10 for your appearing today. We really, really  
11 appreciate all of your engagement. I realize  
12 I-MAK has made a number of PTAB challenges in the  
13 past and one point you didn't exactly address  
14 today was your experience there. I'm wondering if  
15 you have any comments on whether you believe that  
16 the scope of patent challenges that can currently  
17 be made to PTAB are sufficient or would you  
18 recommend being able to bring in any additional  
19 grounds for rejection?

20 MR. AMIN: I think first of all the PTAB  
21 is it's very prohibitive for groups or people who  
22 are outside of the commercial sector to afford to

1 bring those challenges. We were fortunate enough  
2 to have the limited funding to bring those  
3 challenges. And I think the first step is  
4 certainly for non-profit groups or actors who are  
5 not in the commercial space should have some kind  
6 of lower fee structure to be able to do it. I  
7 think there may be something like that even when  
8 applicants file patents they have a different fee  
9 structure. I think for groups who are like  
10 whether they'd be patient groups, or consumer  
11 groups, or whatever, there should be a lower fee.

12 I think in terms of the institution of  
13 the challenges that we made, we didn't get any  
14 instituted. And I felt in some ways that we were  
15 almost prejudiced against because we were actually  
16 challenging the patents as a group who has  
17 actually voiced a lot of concerns about some of  
18 the patent abuses. I'm not saying -- I'm not  
19 implying intention there, I'm just saying that's  
20 how we felt because when Gilead actually  
21 responded, the first thing they did was to attack  
22 our expert and saying that he's anti-patent. And

1 I think that doesn't help the conversation. So, I  
2 would just kind of leave those two comments there  
3 in terms of our experience.

4 MR. SALIMI: Hi. One quick question on  
5 the polymorphs. If the jurisprudence hasn't  
6 changed, under what authority does the U.S. have  
7 to find these polymorphs prima facie obvious?

8 MR. AMIN: Yeah, that's a good point and  
9 I recognize it. But I think it should actually be  
10 recognized within the context of what the FDA  
11 requires. So, I think there should be some change  
12 in practice there. Whether that be done from the  
13 legislature, whether it be due through the USPTO  
14 and FDA to change the guidance of how they work.  
15 I do recognize that current jurisprudence is --

16 REPORTER: Could you turn your mic back  
17 on, please?

18 MR. AMIN: -- that current jurisprudence  
19 is debatable. But I think actually it's important  
20 to recognize if you look at the roster of experts  
21 who testify on these cases, most of them are  
22 making a handsome living testifying about

1       polymorphs. And so, the question then remains is  
2       that really true independent evidence experts,  
3       which is a different issue. But, you know, the  
4       idea that jurisprudence is correct on this, you  
5       know, if we had independent experts outside of  
6       whichever actors involved in the litigation, we  
7       may have actually a different assessment of this.

8               JUDGE HORNER: Okay. I think we're  
9       going to have to leave it at that unless our FDA  
10       folks have any questions?

11              MR. RITTERBECK: I just have a few  
12       questions.

13              JUDGE HORNER: Go ahead.

14              MR. RITTERBECK: Thanks. I'm looking at  
15       your suggestion number three, your recommendation  
16       number three, and I'm just curious, the last line  
17       says this would require FDA to share the IND  
18       materials with the PTO. Why would it require FDA  
19       to share the materials with the PTO as opposed to  
20       that onus being on the applicant itself?

21              MR. AMIN: Well, unless there's --  
22       because I don't think the applicants in the



1       current, they will try and delay and if the PTO  
2       has no idea about the polymorph testing that's  
3       happened and what's actually what they found as a  
4       result of in their ability to get the IND, how  
5       will the PTO ever know?

6               MR. RITTERBECK: Okay, thanks.

7               MS. TILL: Can I follow --

8               MR. AMIN: So, it's a way --

9               MS. TILL: Can I --

10              MR. AMIN: -- it's a way to just sort of  
11       it's an alert system in saying, you know, we have  
12       received this information about this kind of  
13       polymorph related to this drug or this, you know,  
14       and then it kind of puts the onus on the applicant  
15       to kind of show up.

16              MS. TILL: I just wanted to follow-up on  
17       that. So, if the polymorph information has been  
18       submitted to FDA as part of an IND and it's held  
19       in confidence, what statute or provision requires  
20       that applicant or that marketing applicant or that  
21       potential patent applicant to immediately file  
22       their patent application?

1                   MR. AMIN: There is none. And I think  
2                   that's the gaping hole in this issue and that's  
3                   what I'm trying to raise.

4                   MS. TILL: All right, thank you.

5                   MR. AMIN: To use a lawyer speak, we  
6                   found a loophole. You know, I did this as  
7                   practice for 10 years, so.

8                   MS. TILL: Thank you.

9                   JUDGE HORNER: Our next speaker is Mr.  
10                  Hans Sauer from the Biotechnology Innovation  
11                  Organization, BIO. Mr. Sauer.

12                  MR. SAUER: Thank you, Judge Horner, at  
13                  the Patent Office. Good morning. I'm pleased to  
14                  offer remarks this morning.

15                  Most of BIO's members are small  
16                  development stage companies that do not yet have a  
17                  product on the market and that rely on robust IP  
18                  rights in order to access capital, engage in  
19                  partnering and licensing, and advance innovative  
20                  health solutions through the development chain.  
21                  The chances of successfully developing a new  
22                  therapy are less than 10 percent at a cost

1       exceeding \$1 billion over an almost 10-year  
2       development process. Robust and reliable patent  
3       rights are crucially important if private  
4       investment in healthcare innovation is to be  
5       sustained in the face of such costs and risk.

6               Thanks at least in part to a robust and  
7       principled U.S. patent system, more new therapies  
8       are invented and developed in the United States  
9       than in the rest of the world combined. It is  
10      unsurprising that questions about how to sustain  
11      the biomedical innovation engine in the United  
12      States would eventually come into political focus.  
13      In order to execute on the President's drug  
14      pricing agenda, the PTO has issued multiple  
15      Federal Register Notices seeking comments on a  
16      great diversity of proposals to change the way  
17      patents would be examined, reviewed, and enforced.  
18      Proposals range from changing continuing  
19      application practice, to terminal disclaimers, to  
20      PTAB proceedings, patent term extension,  
21      information disclosure statements during patent  
22      prosecution, restriction practice, Orange Book

1 listing, use codes, skinny labeling, and so on.

2           While it is clear that these proposals  
3 are responsive to political narratives and  
4 concerns, the scope and contours of the underlying  
5 problems are subject to debate and poorly  
6 substantiated at this stage. For example, you  
7 have heard that biopharmaceutical companies  
8 procure unusually large numbers of patents. They  
9 do not. In fact, normalized to R&D spend  
10 biopharmaceutical companies procure fewer patents  
11 than comparable businesses in other technologies.  
12 By some accounts patenting intensity in the  
13 biopharma space is around 1/10 of that in  
14 high-tech or communication technology, for  
15 example.

16           Nor are biopharmaceutical patents of  
17 doubtful quality. In fact, pharmaceutical patents  
18 are invalidated less often in litigation, around  
19 25 percent of the time, compared to 40 to 45  
20 percent across all industries.

21           Patent counting exercises are frequently  
22 referenced in public debate but we believe they

1 are neither particularly accurate nor particularly  
2 relevant. Biopharmaceutical companies do not  
3 accumulate unusual numbers of patents associated  
4 with individual products. There are golf balls  
5 with 60 patents on them. Vacuum cleaners with  
6 hundreds. Even cream cheese with seven patents.  
7 Biopharmaceutical products and advanced therapies  
8 are no different from other complex products in  
9 other technologies in this respect.

10 The average number of patents for new  
11 chemical entity drugs in the Orange Book is around  
12 five, not hundreds. The median number of patents  
13 that have been litigated in biosimilars disputes  
14 is less than 10, not hundreds. And importantly,  
15 narratives of everlasting patent monopolies have  
16 consistently avoided looking at actual dates of  
17 generic and biosimilar entry, even though this  
18 information is available and has been studied.

19 A published assessment of the UC  
20 Hastings so-called ever-greening database, for  
21 example, found many innovator drugs that are  
22 listed as supposedly still under monopoly, when

1       they in fact, have had generic competition for  
2       years. The purported innovator monopoly periods  
3       were found to be off by an average of seven years  
4       relative to the dates of actual generic market  
5       entry.

6               If claims to pervasive so-called  
7       ever-greening are correct, we would expect to see  
8       increasingly long periods of market exclusivity  
9       and increasingly later entry of generic  
10       competition. This is not the case. The empirical  
11       period of actual pharmaceutical market exclusivity  
12       from approval of a new chemical entity to the date  
13       a generic enters the market has been studied since  
14       the 1990s and has been found be stable at around  
15       12 to 13 years, not decades. It would be a  
16       fallacy to say that patenting data proved the  
17       emergence of ever- expanding pharmaceutical  
18       monopolies at the need for expansive policy  
19       change.

20               BIO looks forward to engaging with the  
21       PTO and the FDA on the empirical evidence. BIO's  
22       members welcome and support agency collaboration

1       that helps agencies better do their jobs. On the  
2       topic of FDA-PTO collaborations, specifically, we  
3       understand that FDA already has authority to  
4       inspect PTO records for purposes in enforcing the  
5       FDCA. And the PTO in turn has the ability to  
6       request full and complete information from the FDA  
7       relating to questions raised by any drug patent  
8       application and even to have the FDA conduct  
9       additional research into such questions. Patent  
10      examiners are able to require such information  
11      directly from applicants if they deem it to be  
12      reasonably necessary to the examination of an  
13      application. And applicants are under a duty to  
14      disclose material information under Rule 56.

15               Given these tools already being  
16      available to the two agencies, it would be helpful  
17      to better understand what it is in the FDA record  
18      that the PTO would expect to find. We know  
19      empirically that FDA regulatory dossiers are not  
20      very efficient or fruitful sources of prior art  
21      that cannot be accessed from other sources.  
22      Well-heeled and sophisticated litigants in patent

1       litigation have reviewed their adversary's  
2       regulatory filings for decades with few instances  
3       of finding killer prior art.

4               And even with respect to inconsistent  
5       statements the PTO points to two cases, not more,  
6       a 30-year-old case of a 510(K) medical device  
7       applicant and a more recent case of a 505(b)(2)  
8       new drug applicant. In each instance, those  
9       applicants relied for FDA approval on prior art  
10      predicate devices or reference drugs that had been  
11      withheld from the PTO. These are hardly typical  
12      scenarios in the innovator biopharmaceutical  
13      industry and we think they are a thin reed for  
14      instituting systemic change.

15             Nonetheless, the PTO should, of course,  
16      have access to material information. There may  
17      indeed be instances where the FDA could assist the  
18      PTO in finding prior art, perhaps non-patent,  
19      non-publication prior art that may not be  
20      identifiable from other sources. Like, for  
21      example, the specifications of the predicate  
22      devices or the reference drug at issue in the



1 Bruno and Belcher cases that are cited in the  
2 Federal Register Notices.

3 We caution, however, against witch hunts  
4 for seemingly inconsistent statements because  
5 consistency or inconsistency is going to be  
6 extremely difficult to assess given the varied  
7 standards between the two agencies. Something may  
8 be non-obvious under the PTO's standards, but  
9 still qualify as a predictable, reliable, safe,  
10 and effective outcome in support of a drug  
11 applicant. Sorting through all of the FDA's  
12 written materials would be an enormous burden on  
13 agency staff and applicants, causing much delay  
14 while unlikely to prove new or additional  
15 information relevant to patentability in the  
16 aggregate. Thank you for your attention.

17 JUDGE HORNER: Thank you very much for  
18 your comments. I'll open it up to the panel for  
19 any questions. Any? Yes, go ahead.

20 MS. DAVIS: Thank you for your remarks.  
21 I have actually a request instead of a question.  
22 I saw you submitted your written remarks, but if

1       you have anything additional you can submit to the  
2       docket about some of the figures you cited like  
3       average numbers of patents, that would be really  
4       helpful. Because that's different than what I  
5       think we've seen in our own analysis. So, it  
6       would be helpful to see how you looked at it and  
7       where that figure comes from.

8               MR. SAUER: Yes.

9               MS. DAVIS: Thank you.

10              MR. SAUER: Thank you.

11              MS. TERROT: Hi. I had a question. You  
12       mentioned that there's been tracking of the  
13       average time to generic entry and that it stayed  
14       relatively stable. Have you studied the  
15       litigation costs relative to other development  
16       costs? Or, you know, has the number of patents  
17       asserted in Hatch-Waxman litigation evolved? Or  
18       have you studied how, you know, how much of a  
19       relative financial burden the litigation is to  
20       getting a generic to market?

21              MR. SAUER: Okay. So, on the financial  
22       burden, I don't have that information. We did

1 look, however, over the years at how many patents  
2 are listed in the Orange Book for, in particular,  
3 new chemical entities. That's not just us. I  
4 mean, this has been studied a number of times over  
5 the years. I do think it's true that over time  
6 there's been a moderate increase in the number of  
7 patents that appear in the Orange Book. So, 20  
8 years ago the average number may have been  
9 something like three patents per drug, and it is  
10 now more around five. So, there has been an  
11 increase over time.

12 The time to a generic entry has stayed  
13 similar, as I said. What has also changed is the  
14 frequency and the timing of generic challenges,  
15 and particularly a paragraph 4 challenges, which  
16 now occur earlier than they did 20 years ago. So,  
17 I think one way to look at this would be to say  
18 that both sides of the industry, at least in the  
19 Hatch-Waxman context, have over time evolved their  
20 strategies. And the net effect on the timing of  
21 generic entry as a result has stayed the same.  
22 That would be our interpretation of the data. But

1       that too will be something that would submit on  
2       the 6th when the time comes for written comments.

3               MR. SALIMI: I guess I would -- I  
4       appreciate the fact that you said the difference  
5       -- there has been some decade between the Bruno  
6       and Belcher case. So, that means the system is  
7       somewhat working. But do you have any new ideas  
8       for private practitioners to have a better  
9       communication with the regulatory side and the  
10      litigator side so there won't be any Belcher case?

11             MR. SAUER: Yeah. Do I have ideas? I  
12      think those will -- the way this would be  
13      implemented -- well, first of all, I think you're  
14      right. You know, we haven't seen a lot of case  
15      law, but we do know that defendants in litigation  
16      have been looking for exactly this kind of  
17      scenario for a long time and it doesn't appear  
18      often. In my personal opinion, I think the  
19      Belcher and the Bruno cases are examples where the  
20      system worked. If this were to happen routinely,  
21      we would have heard about it more often. And so,  
22      these cases I don't think are tips of an iceberg.

1       They are more signs that the system can actually  
2       work if you have motivated litigants. No, not  
3       everything will have been caught over time.

4               With respect to implementing practice  
5       changes in the industry, I hear a lot from our  
6       member companies who are wondering about the  
7       Federal Register Notices, the scope of the  
8       obligations and duties. Companies are different  
9       in size and organization. Belcher, I think, was a  
10      very small company. You could see from the record  
11      that the people involved with the prosecution of  
12      the application had an unusually strong input in  
13      the FDA. They even shared jobs and  
14      responsibilities. That is often not the case in  
15      pharmaceutical companies.

16             So, I can tell you when I worked  
17      in-house as a patent lawyer, I had some patent  
18      lawyer colleagues and I would sit in on product  
19      development teams. But I had no line of sight  
20      into what everybody else in the team was writing  
21      or communicating to colleagues at the FDA or  
22      frankly others like clinical investigators because

1       why stop at the FDA record?

2               So, to expect that the patent people in  
3       the company have a line of sight into what some  
4       medical writer communicates to another colleague  
5       in their space or maybe a clinical investigator  
6       sometimes it's very hard to expect of a company to  
7       be able to do this and to control communications.  
8       But we are certainly thinking through these  
9       questions. We agree that there shouldn't be  
10      inconsistent statements. But we also think that  
11      finding prior art, rather than inconsistent  
12      statements, I think prior art is the more  
13      important of the two kinds of information to find.  
14      And then I'll stop.

15             I will say what we've seen when we  
16      looked in litigation records for typical  
17      scenarios, what seems to be common is that prior  
18      art is usually sourced elsewhere. It emerges  
19      somewhere in the litigation. And then defendants  
20      want to know and want to access the FDA record to  
21      see not the prior art, but they want to know what  
22      the patentee said about that prior art. So,

1 finding the prior art is one thing. Wanting to  
2 know what was said about it is a different  
3 question. And that's not always relevant to  
4 patentability.

5 JUDGE HORNER: Thank you. We're going  
6 to move on to our next speaker who is a virtual  
7 speaker, Ms. Shaina Kasper, from T1International.  
8 And while we're waiting for her image to come up,  
9 I want to make a shameless plug for an event that  
10 we're planning on February 23rd. We're going to  
11 be doing a panel discussion. It's going to be  
12 moderated by the vice chair for the AIPLA Food and  
13 Drug Committee. And we'll have panelists from the  
14 Office of Patent Legal Administration and the  
15 Office of Enrollment and Discipline to talk about  
16 the Federal Register Notice that the Office issued  
17 on duty of disclosure and duty of reasonable  
18 inquiry.

19 So, we're fielding questions now from  
20 the public that we could provide to that panel.  
21 So, if you have questions, specific questions from  
22 members of your group that you want to pose to the

1 panel, we're collecting those questions now.

2 All right. And hopefully we will get

3 Ms. Kasper.

4 MS. KASPER: Can you hear me okay?

5 JUDGE HORNER: We can hear you. We  
6 can't see you yet. Yes, there you are, wonderful.

7 MS. KASPER: Great. My name's Shaina  
8 Kasper. I'm a patient living with type 1  
9 diabetes, insulin dependent. I'm also the policy  
10 manager for T1International. And I'm apologize  
11 I'm not able to appear in person as planned. It  
12 seems that while I don't have COVID, I have been  
13 taken out by the common cold.

14 So, I want to start off just by sharing  
15 a little bit about our organization.  
16 T1International is a global diabetes advocacy  
17 organization led by people with diabetes, poor  
18 people with diabetes. T1International believes in  
19 a world where everyone with diabetes no matter  
20 where they live has everything they need to  
21 survive and achieve their dreams. We accept no  
22 funding from pharmaceutical companies and provide



1       advocacy training and support to all Insulin for  
2       All advocates.

3               In the U.S., T1International has 41  
4       state-led Insulin for All chapters and growing,  
5       and we have three working groups with national  
6       membership. Communities of Color Working Group  
7       focuses on ensuring Insulin for All is for all and  
8       part of our organizational efforts to seek and  
9       learn from and incorporate the lived experience  
10      that has historically excluded communities at the  
11      center of our organization and our work.

12             Families United for Affordable Insulin  
13      is both an advocacy and support group for  
14      advocates with lost loved ones due to insulin  
15      rationing. And the Federal Working Group is  
16      focused on addressing the insulin price crisis  
17      through legislative and administrative policy  
18      changes.

19             So, I want to start off by sharing some  
20      about why patent review reform is a priority for  
21      T1International's Federal Working Group. One  
22      hundred years ago this week, in January of 1923,

1 the discoverers of insulin sold the patent of  
2 insulin for \$1 saying insulin does not belong to  
3 me, it belongs to the world. Rather than the gift  
4 it was intended to be, their discovery has become  
5 the poster child for pharmaceutical price gouging.

6 Over the past 100 years, while insulin  
7 has improved incrementally, many of the newest  
8 insulins are still decades old. So, one example  
9 of the many reasons why long-acting insulin  
10 chloroquine prescriptions have been so expensive  
11 is because Sanofi had filed 74 patent applications  
12 on the drug Lantus, effectively blocking generic  
13 competition for 37 years. This example has been  
14 written on extensively including with an I-MAK  
15 report published in 2018 on the topic.

16 Unfortunately, it is not unique among  
17 the insulins or among other pharmaceuticals.  
18 Pharma has created big thickets of patents around  
19 them allowing them to maintain a monopoly. And  
20 this patent thicketing, along with the pay for  
21 delay set of patent settlement dispute agreements  
22 and more, has hindered true competition and thus

1       lowering the prices of drugs.

2               The PTO has made mistakes, I believe, by  
3       allowing for additional patents for trivial  
4       obvious variations on older drugs and enabling  
5       companies to maintain these monopolies. These  
6       unfair extensions of monopoly protections have  
7       been keeping prices high. The PTO must share  
8       information with the FDA to stop new patents on  
9       trivial obvious variations on old drug.

10              Lantus insulin patents are a good case  
11      to be for why this is important. The priority  
12      claim on Lantus was in 1988, with a first patent  
13      filing for Lantus in 1994, and approved by the FDA  
14      in 2000. Lantus was revolutionary when it came  
15      out and dramatically changed patient care. And if  
16      the PTO had talked with the FDA back then, I think  
17      they would have agreed this was an innovative, and  
18      non-obvious, and medical benefit. And rightly,  
19      Sanofi secured monopoly protection for Lantus in  
20      the U.S. for years just on the basis of that  
21      primary patent, which expired in 2015.

22              However, Lantus wasn't just covered by

1     one patent. Almost 95 percent of the total patent  
2     applications, 69 out of 74 on Lantus, were filed  
3     after the drug was approved in 2000. One  
4     exemplary patent filed when Lantus was first  
5     approved covers a supposedly new and improved  
6     delivery system for the insulin patent, the dose  
7     style sleeve between the housing and the piston  
8     rod with helical grooves. This patent's effective  
9     filing date was 2004, but the patent doesn't  
10    expire until 2027 or 2028. This patent helped  
11    Sanofi force Merck, a would-be competitor, to give  
12    up on its lower cost insulin Glargine products  
13    back in 2018. So, this patent seems to have  
14    played a role in preventing competition and  
15    protecting Sanofi's monopoly.

16               Before going on, I must note that there  
17    are now lower cost biosimilar alternatives to  
18    Lantus on the market, including the form of  
19    Viatris's assembly product. Although the product  
20    isn't available everywhere. Merck gave up but  
21    Viatris, formerly known as Mylan, kept going and  
22    ultimately did get to market. But this patent

1       helped Sanofi protect its monopoly, delay  
2       competition, and keep one would-be competitor off  
3       the market altogether. All of which serves to  
4       keep Sanofi's profits high and profits high.

5               I am not a mechanical engineer so I  
6       don't feel I'm really qualified to opine here.  
7       But the patent invention of the dose style sleeve  
8       between the housing and the piston rod with  
9       helical groove does not appear to me to be a  
10      radical step forward in insulin delivery  
11      technology. I don't have an insulin -- a Lantus  
12      insulin prescription anymore. But here is my  
13      Levemir dose style sleeve with the helical groove.  
14      Pretty similar to the Novalog pen, as well as the  
15      reusable Novalog pen here as well, as well as this  
16      mechanical pencil, as well as this Chapstick that  
17      are also all purchased at CVS.

18             It is not clear to me as a patient, what  
19      medical benefits, if any, Sanofi's patented  
20      delivery device system does provide to patients.  
21      These patents do not constitute a novel innovation  
22      to me.

1                   We need consistent representation  
2   between the FDA and the PTO to ensure that PTO  
3   examiners are trained on what FDA documents to  
4   review when examining patent applications for  
5   situations like this. When Sanofi made small  
6   modifications to its patent, did it characterize  
7   these modifications to the FDA? PTO should update  
8   its regulations to make it really crystal clear to  
9   patent applicants that those applications have an  
10   ongoing duty to disclose what they've said to the  
11   FDA about their products.

12                  This example also highlights the  
13   importance of independent patient and consumer  
14   group perspectives in these processes. Had there  
15   been an opportunity for independent patient  
16   perspectives on the Lantus example, we could have  
17   shared back in the '90s that having this  
18   long-acting insulin like Lantus is non-obvious,  
19   novel, innovative. And had we been consulted  
20   about the groove improvements we likely could have  
21   shared that this was not a non-obvious. It was  
22   not a major advance. It did not have a clear

1       medical benefit to patients like me, as my  
2       colleague Kevin Wren shared earlier.

3               A few years ago, because of this patent  
4       thicketing and Sanofi's high prices, I went into  
5       the pharmacy to pick up my prescriptions and had  
6       to turn around without filling these  
7       prescriptions. Before I hit my deductible usually  
8       in February, I've had to pay that full cost of  
9       Lantus. Had to pay that full cost of the patent  
10      thicketing, which has cost me money, but also my  
11      time, my stress, anxiety, and led to insulin  
12      rationing, with serious health consequences.

13             Insulin patents provide a clear case  
14      study on the important need for constituent  
15      representation between the FDA -- and for  
16      consistent representation between the FDA and the  
17      PTO, as well as constituent support. And I hope  
18      this will provide some real-world grounding and  
19      ongoing and further conversations. Thank you so  
20      much for your time.

21             JUDGE HORNER: Thank you, Ms. Kasper.  
22      Do we have any questions? I think we have a

1 question on the end.

2 MS. FERRITER: Thank you very much for  
3 your testifying today and the time that you took  
4 to write the written submission. The USPTO, as  
5 has previously been mentioned, does have a process  
6 by which we welcome third-party submissions  
7 related to patent applications. And I'm wondering  
8 if you or your organization has ever taken  
9 advantage of that process?

10 A few years ago, we changed the process  
11 to eliminate the fee. And right now, we have a  
12 really handy tool where you can go online and make  
13 the submission. And we would really welcome the  
14 information that your organization could provide  
15 related to novelty and non-obviousness. Thank  
16 you.

17 MS. KASPER: Yeah, I think in order to  
18 really get more patient perspectives and voices  
19 involved in the process, there needs to make --  
20 the process needs to be even more simplified and  
21 easy to use. I think the third-party submission  
22 process is still extremely complex and easy to



1 use. You know, we are not attorneys. We are not  
2 mechanical engineers. We are patients with  
3 chronic conditions and being able to access and  
4 use these submission processes by, you know, being  
5 able to share our lived experiences and stories is  
6 -- doesn't feel welcome in the current submission  
7 process.

8 And I can provide more in additional  
9 written comments including our patient -- oh, my  
10 gosh, what's it called -- our -- at  
11 T1International, we have a ethical patient  
12 engagement principles that I can also share that  
13 could be helpful for this. And would love to  
14 continue the conversation of how to potentially  
15 improve that process, as well as updating  
16 additional processes for improvement.

17 JUDGE HORNER: Sorry, thank you. I have  
18 one more question. You mentioned a couple of  
19 times when discussing about patentability that it  
20 should have medical benefits for patients. Are  
21 you proposing that, I mean, the standard for  
22 patentability is novelty and non-obviousness. But

1 the patentability standard does not require an  
2 examination of whether the claimed invention has  
3 medical benefits per se. Is that something your  
4 group is advocating for that you think the law  
5 should be changed in that regard?

6 MS. KASPER: Yeah, I do not -- I'm not  
7 making a request to reopen the law. I know that  
8 has been in discussion and I recognize this is not  
9 the audience for that, as well. I do think  
10 medical benefit is the primary novel reason for  
11 looking at patents and that should be under  
12 consideration as well. But, no, I'm not. I'm not  
13 --

14 JUDGE HORNER: Okay.

15 MS. KASPER: -- suggesting that we  
16 reopen the law, the legal framework.

17 JUDGE HORNER: Thank you. Thank you.  
18 All right. Thank you for your time today.

19 MS. KASPER: Thank you.

20 JUDGE HORNER: And we'll go to the next  
21 speaker. Our next speaker is Professor Adam  
22 Mossoff. He's with the George Mason University

1 Antonin Scalia Law School. Professor Mossoff.

2 PROF. MOSSOFF: All right. Thank you.

3 Thank you for this opportunity to speak at this  
4 listening session today on USPTO-FDA collaboration  
5 initiatives. Now, in my brief remarks this  
6 morning, I'd like to emphasize the importance of  
7 evidence-based policy making when it comes to any  
8 new proposed regulatory initiatives in the patent  
9 system.

10 As economists and historians have shown,  
11 the patent system has driven the U.S. innovation  
12 economy for over 200 years. And this is  
13 dramatically evidenced in the pharmaceutical and  
14 biotech revolutions of the last 100 years. Well  
15 over 1/2 of all new drugs are invented in the  
16 United States. And a significant majority of R&D  
17 funding of the biomedical research that creates  
18 these new drugs is private, not public.

19 Thus, anyone proposing new regulations  
20 that would impose costs on all innovators who use  
21 the patent system has the burden to prove the  
22 necessity for these regulations by evidence-based

1 studies that follow rigorous norms of statistical  
2 or scientific analyses. Without this evidence, we  
3 risk creating unnecessary and costly regulatory  
4 barriers for all innovators who rely on effective  
5 and reliable patent rights to recoup billions in  
6 R&D investments and who also rely on these same  
7 patents to facilitate the licensing and other  
8 commercialization activities that are necessary to  
9 translate new drug discoveries into real-world  
10 therapeutic treatments that save lives and improve  
11 the quality of daily life for everyone.

12 Now, with this policy and evidentiary  
13 principles in mind, I am concerned that the policy  
14 debate over drug patents that is driving the calls  
15 for these new regulatory initiatives between the  
16 USPTO and FDA has been defined largely by ill-  
17 conceived rhetoric like patent thickets and  
18 ever-greening. Now, I call these terms rhetoric  
19 to distinguish them from proper conclusions  
20 carefully derived from rigorous evidence- based  
21 analyses and statistical studies of the patent  
22 system generally and of drug patents specifically.

1                   Now, I detailed this concern recently by  
2     identifying significant and unexplained  
3     discrepancies in the claims about drug patent  
4     numbers in a policy brief I published last year  
5     titled, Unreliable Data Have Infected the Policy  
6     Debates Over Drug Patents. Now, in this policy  
7     brief, I identified discrepancies by orders of  
8     magnitude between some of the total drug patent  
9     numbers that are asserted by I-MAK in its studies  
10    and publications over the past several years, and  
11    those found in public government sources like the  
12    FDA's Orange Book or in court opinions.

13                  Now, I don't have time to review all of  
14    the examples and so, I'll only give one or two to  
15    illustrate these profound empirical concerns.  
16    Now, one example addresses Lyrica, a drug produced  
17    by Pfizer to treat pain caused by nerve damage  
18    from diabetes, shingles, or other injuries. Now,  
19    I-MAK claimed in its 2018 report that 68 patents  
20    cover Lyrica. But when you look at the Orange  
21    Book, it identifies four patents. In fact, only  
22    three really in reality because one of those

1 patents is a reissue patent and so, it's not even  
2 a separate patent.

3 Now, I-MAK also asserted in that same  
4 report that Pfizer will retain exclusive rights  
5 over Lyrica until 2038, a whopping 10 years beyond  
6 the expiration date of the patents listed for  
7 Lyrica in the Orange Book. But the main patent on  
8 the active ingredient in Lyrica expired in  
9 December of 2018, the same year that I-MAK  
10 released its report. And the FDA approved nine  
11 generic versions of Lyrica the following year in  
12 2019. As one media outlet reported in 2019, the  
13 "patent cliff is here" for Pfizer's Lyrica. Yet,  
14 I-MAK claimed that Pfizer has exclusivity in  
15 Lyrica for another 20 years after entry of  
16 multiple generic versions of Lyrica.

17 Now, another example that I identified  
18 in my policy brief concerned the drug Eliquis.  
19 Now, Eliquis is a drug produced by Bristol-Meyers  
20 Squibb and Pfizer that reduces the risk of  
21 life-threatening blood clots caused by irregular  
22 heartbeats following surgery. I-MAK has asserted

1 in its various reports that there are somewhere  
2 between 27 and 31 patents covering Eliquis. It  
3 doesn't explain the differences or how it derived  
4 the basis for these different numbers of patent  
5 numbers but it's somewhere between 27 and 31.  
6 Again, when one looks at the FDA Orange Book, one  
7 finds three patents covering Eliquis.

8 Now, these are just a few of the  
9 examples of vast discrepancies in numbers. And  
10 again, these are unexplained discrepancies by  
11 orders of magnitude. These are not mere rounding  
12 errors that one might find as a result of dealing  
13 with significant numbers. Now, last year Senator  
14 Tillis prompted by my policy brief and other  
15 studies and reports, sent letters to the USPTO, to  
16 the FDA, and to I-MAK.

17 Now, in addition to concerns expressed  
18 about the quality and reliability of I-MAK  
19 numbers, Senator Tillis also identified serious  
20 concerns about the evergreen drug patent search  
21 database that's at UC Hastings. One example that  
22 he referenced is that this evergreen drug patent

1 search database, that's its official title, has  
2 listings for aspirin, despite aspirin being  
3 available in generic form for over 100 years.

4 Now, one very important revelation that  
5 came out of Senator Tillis' letters and I-MAK's  
6 responses is that I-MAK has been counting both  
7 pending and abandoned patent applications in its  
8 total patent numbers. And this is not something  
9 that it has always acknowledged in its annual  
10 reports. Yet, all drug companies, generic and  
11 branded drug innovators, and patent lawyers know  
12 that abandoned or even pending patent applications  
13 are not the same as issued patents. They do not  
14 confer exclusivity.

15 Just as any patent -- and by the way,  
16 this applies just as much to claims about  
17 continuation practices -- any patent lawyer and  
18 any drug company knows that a continuation does  
19 not extend a patent term. And yet, we're seeing  
20 similar repeated claims about continuation  
21 practices now as we have heard in the context of  
22 patent thickets and ever-greening.



1           So, in sum, and in my brief time this  
2 morning, I really would believe and I hope I have  
3 highlighted two key points that should guide  
4 policymaking by government officials. First, the  
5 evidentiary burden for proving systemic problems  
6 requiring systemic changes via regulatory  
7 initiatives to the patent system is on those  
8 proposing the systemic changes. And second, the  
9 data claims about drug patents driving the policy  
10 debates are rife with serious questions about  
11 their veracity. The patent system is too  
12 important for inventors, the U.S. Innovation  
13 economy, and the enumerable people who benefit  
14 from innovations in healthcare.

15           Alan Marco, former chief economist at  
16 the USPTO, when he was chief economist, argued  
17 repeatedly that we need to ensure that there is  
18 evidence-based policymaking as opposed to what he  
19 referred to policy-based evidence making. And  
20 this is a very serious concern. Or to invoke the  
21 more simple point made in the healthcare context,  
22 we should follow the maxim, first, do no harm.

1 Thank you.

2 JUDGE HORNER: Thank you, Professor  
3 Mossoff. I have one question to start out and  
4 then I'll open it for the rest of the panelists.

5 PROF. MOSSOFF: Sure.

6 JUDGE HORNER: The idea of counting  
7 patents and looking at patent term, is that a  
8 sufficient way to look at a patent landscape of a  
9 product without consideration of patent scope? Or  
10 is patent scope an important part of an  
11 examination of a patent landscape for a product?

12 PROF. MOSSOFF: That's a great question.  
13 And as a general matter, just patent counting as  
14 such has been repeatedly identified as extremely  
15 problematic by economists. There are numerable  
16 confounding variables that would apply in patent  
17 counting. By the way, assuming you're counting  
18 actually issued patents, not abandoned patent  
19 applications and/or pending patent applications.  
20 Because there are many reasons why people obtain  
21 patents. Patents have different scope. They  
22 apply to different types of products and different

1 types of inventions. Some are methods, some are  
2 on, some are products, right? Some are  
3 compositions of matter.

4 And so, you know, there's a real concern  
5 with just saying, well, here's a list of patents  
6 that we found. And yet, those are easy to  
7 understand numbers, especially when they seem to  
8 be very large. And they have a hold on people's  
9 imagination. And that's why I think we see people  
10 easily invoking those numbers that we've heard  
11 today and we've seen even on the Hill and even  
12 among some professors, unfortunately.

13 JUDGE HORNER: Thank you. Do any other  
14 panelists have questions? Karin.

15 MS. FERRITER: So sort of building on  
16 that, do you think that counting patent use codes  
17 is at all useful proxy, or does it have the same  
18 problem that Linda was alluding to of not  
19 necessarily understanding scope?

20 PROF. MOSOFF: Yeah. That's an  
21 interesting question, I hadn't thought of it,  
22 which I'm thinking about your question. I think

1       it still kind of relates, it could still relate to  
2       some of the underlying concerns although might  
3       provide some more granular assessment of what  
4       types of patents you're counting. But I think  
5       you'd still end up with some of the similar  
6       concerns and related concerns about why those  
7       patents were being obtained, what their actual  
8       function is and what their role is actually in the  
9       specific art in which they're being deployed.

10               JUDGE HORNER: Thank you. And now we'll  
11       move to our last speaker, Ms. Carol Nielsen from  
12       Nielsen IP Law, speaking on behalf of the American  
13       Intellectual Property Law Association. Ms.  
14       Nielsen.

15               MS. NIELSEN: Hi. I am Carol Nielsen,  
16       and I am of Nielsen IP Law, but I am here on  
17       behalf of AIPLA and making the statement on behalf  
18       of AIPLA, not my law firm or its clients.

19               I've been a patent practitioner, well  
20       I've been a lawyer for over 30 years, and I think  
21       I got my registration number, I was trying to  
22       remember but it's '93 or '94. And my perspective,

1       and many of our members, is as a patent  
2       practitioner.

3               The American Intellectual Property Law  
4       Association is a national bar association of  
5       approximately 7,000 members who are engaged in  
6       private or corporate practice in government  
7       service and in the academic community. AIPLA  
8       thanks the offices for the invitation to comment  
9       on issues relating to pharmaceutical patenting and  
10      for the opportunity to be heard in this listening  
11      session.

12             AIPLA intends to submit written comments  
13      that address a number of the questions presented  
14      by the patent office but today we'll speak  
15      primarily to Question 2. That is what mechanisms  
16      could assist patent examiners in determining  
17      whether parent applicants or owners have submitted  
18      inconsistent statements to the USPTO and the FDA.  
19      And whether such mechanisms present  
20      confidentiality concerns.

21             To be clear, AIPLA, like the USPTO,  
22      believes that a patent examiner needs to know

1       about inconsistent statements. That is,  
2       statements that can affect his or her  
3       determination that a patent claim is allowable and  
4       that a patent can be granted on that claim.  
5       However, AIPLA is not aware that inconsistent  
6       statements are a wide-spread problem or that  
7       inconsistent statements have resulted in any  
8       significant number of patents being granted that  
9       should not have been granted. AIPLA believes the  
10      existing duty of candor to the U.S. Patent Office  
11      provides a substantial deterrent not to make a  
12      material inconsistent statement.

13               But in answer to the question, one  
14      mechanism to be considered could be to permit the  
15      patent office, the U.S. Patent Office, to make  
16      direct requests to the FDA regarding specific  
17      inventions and to request information that may be  
18      material to patentability. The request could come  
19      after a specific issue comes to light during  
20      patent prosecution or when a patent examiner is  
21      aware of documents containing information material  
22      to patentability that are on file with the FDA.

1 While it's already possible for the patent office  
2 to ask applicants for information under Rule 105,  
3 a request for specific information could be made  
4 to the FDA in a similar manner as requests are  
5 made to applicants.

6 The authority under which the patent  
7 office, U.S. Patent Office, and the FDA work  
8 however, are completely different, Title 35 versus  
9 Title 21. Information brought before the USPTO is  
10 related to an invention defined by claims whereas  
11 the FDA is concerned about drug, safety, and  
12 efficacy. Therefore any mechanism requesting  
13 information sharing between these agencies raises  
14 questions about the scope and implementation of  
15 such requests for information.

16 For example, what issues raised in  
17 patent prosecution will mandate the need for  
18 additional information from the FDA? How will the  
19 FDA determine what information to give the patent  
20 office and/or what kind of information can be  
21 subjected to USPTO review? How will trade secret  
22 information submitted to the FDA be handled to

1       avoid public disclosure? Will the patent  
2       applicant be involved in this process? How will  
3       the review of confidential information by the  
4       examiner be documented in the file history, if at  
5       all?

6                AIPLA would appreciate a better  
7       understanding to the answers to these and similar  
8       questions before providing additional comments on  
9       the feasibility of this possible mechanism.  
10      Generally AIPLA is concerned that any attempt to  
11      share information between the agencies, regardless  
12      of the mechanism, will create significant burdens  
13      on both agencies and applicants. We're further  
14      concerned that confidential information will be  
15      disclosed which will put trade secret protection  
16      at risk and will result in a disincentive to  
17      innovation.

18               While avoiding inconsistent statements  
19      is a valid concern, AIPLA believes that the  
20      current duty of disclosure rules work. AIPLA  
21      believes that the duty of disclosing information  
22      to the USPTO that has been disclosed to the FDA



1 are required by the current Rule 56, and it is  
2 clear the law requires that every individual  
3 involved with a patent application be candid with  
4 the USPTO. This duty of candor requires anyone  
5 associated with the prosecution of a patent  
6 application to disclose to the United States  
7 Patent Office information that's material to  
8 patentability, including that information that's  
9 on file with the FDA.

10 The effect of not abiding by these  
11 rules, the deterrent, is very serious,  
12 unenforceability of any subsequently issued patent  
13 right. AIPLA believes that the obligations  
14 associated with the duties of disclosure, candor,  
15 and good faith are clear and are diligently  
16 implemented and administered by the USPTO and  
17 further supported by the judicial branch. Through  
18 the enforcement of associated regulations the U.S.  
19 Patent Office encourages patent applicants to  
20 provide it with accurate and material information.  
21 Inconsistent statements made to the FDA and the  
22 USPTO pose a substantial risk to enforcement of

1       potentially very valuable patent rights. Prudent  
2       applicants thus have a strong incentive to take  
3       precautions to avoid the risk of making  
4       inconsistent statements.

5               On behalf of AIPLA I thank you for your  
6       time and your consideration of these views. And I  
7       also note again that we will continue to consider  
8       these issues and will supplement these comments  
9       with a written comment letter.

10              JUDGE HORNER: Thank you, Ms. Nielsen,  
11       we appreciate AIPLA's involvement in this  
12       discussion and their remarks. Do the panelists  
13       have any questions? No? Everybody's hungry.

14              MS. TILL: The only question that I have  
15       was about if information that is provided to PTO  
16       from FDA records and it is confidential type of  
17       information, currently there's no process in place  
18       at PTO to address keeping it confidential, using  
19       it in some type of rejection of a patent  
20       application. Are you suggesting that the examiner  
21       could review that information and have that  
22       knowledge in order to leverage it in say a request

1       for information from the applicant?

2                   MS. NIELSEN: That's not our suggestion  
3       per se, as I understand it. But our concern is,  
4       well one of them are how are you going to document  
5       that? Once the examiner has confidential  
6       information subject to trade secret protection and  
7       is using that either to say the claims are  
8       allowable or not allowable, then, you know, where  
9       does that information go on the freedom to operate  
10      side on the infringement analysis, which I do as a  
11      practitioner, I will have no idea knowing what the  
12      examiner looked at if that information doesn't  
13      become public in some way and therefore it's kind  
14      of circular, right? I mean what do we do about  
15      that?

16                  MS. TILL: Yeah. I think what you are  
17      saying is how do you know what was in the  
18      examiner's head when they made the determination.

19                  MS. NIELSEN: Well yeah, and I have to  
20      tell you as a patent practitioner we live and die  
21      by the file wrapper. It's very important to us.

22                  MS. TILL: Un-huh.

1 JUDGE HORNER: Great. Thank you. Any  
2 other questions?

3 MR. SALIMI: Yes. Ms. Nielsen, in your  
4 experience when there are like two firms, one  
5 handling the prosecution, one handling the  
6 litigation or before the FDA, these two firms, do  
7 they really communicate with each other or the  
8 materiality of the information to the PTO, or is  
9 there a what they might call like a Chinese Wall  
10 between these two firms? And if that's the case,  
11 is there a better way to communicate between the  
12 two entities?

13 MS. NIELSEN: Okay. I'm here on behalf  
14 of AIPLA and we have not addressed that. But, you  
15 know, who handles what in the patent world, it can  
16 be the same firm that does the litigation and the  
17 prosecution, if that's what you mean law firm, it  
18 can be both. They can do it, it's not always  
19 advisable but both, the same law firm can handle  
20 both. And then usually there's a regulatory  
21 expert. And that's all really I know. I don't  
22 know how the paper flow would go between a law

1 firm environment if that's what you're asking me.

2 MR. SALIMI: I was thinking like if a  
3 firm handles the prosecution side and then there's  
4 another firm that handles the regulatory or if  
5 there's a litigation going on, is there a line of  
6 communication between these two?

7 MS. NIELSEN: No, I would not think so.  
8 And that's my opinion, we haven't discussed  
9 amongst our group at AIPLA.

10 JUDGE HORNER: Thank you, Ms. Nielsen.  
11 We're going to take a break for lunch, we'll  
12 reconvene at 2:00 o'clock for Session 4. If you  
13 haven't already grabbed information out on the  
14 registration table we have some information about  
15 nearby restaurants and also the cafeteria here at  
16 the USPTO is open.

17 (Recess)

18 JUDGE HORNER: I'll go ahead and get  
19 started, it's about 2:00. So a couple of  
20 administrative things. One, for the speakers and  
21 panelists, when you're speaking try to keep close  
22 to your microphones because with these masks

1 sometimes it's difficult when you're far away to  
2 understand and project what you're saying.

3 Also it was called to my attention I  
4 neglected to allow the panelists to introduce  
5 themselves for Session 3, but most of the  
6 panelists for Session 4 are the same so I'll allow  
7 them to introduce themselves. With the exception  
8 of two speakers, or two of the panelists from the  
9 Patent Office for our last panel were Ali Salimi  
10 and Mary Till, they're with our office of Patent  
11 Legal Administration. I apologize to them for not  
12 allowing them to introduce themselves.

13 But before we get started on Session 4,  
14 I'll just start at the end of the table, panelists  
15 if you can introduce yourself with your name,  
16 title, affiliation within the Agency and then your  
17 agency.

18 MR. UNLU: Hi. I'm Mustafa Unlu, I'm  
19 with the FDA Center for Drug Evaluation and  
20 Research, and I'm at the Office of Therapeutic  
21 Biologics and Biosimilars.

22 MS. DAVIS: Hi. I'm Kristin Davis, I'm

1 the Director of the Office of Generic Drug Policy  
2 in the Office of Generic Drugs in the Center for  
3 Drug Evaluation and Research at the FDA.

4 MR. RITTERBECK: Hi everyone. My name  
5 is Dan Ritterbeck, I'm a Regulatory Counsel in the  
6 CDER's Office for Regulatory Policy at FDA.

7 MS. TERROT: Hi, my name is Marianne  
8 Terrot, and I'm an Associate Chief Counsel in  
9 FDA's Office of the Chief Counsel.

10 JUDGE HORNER: I'm Linda Horner, I'm an  
11 Administrative Patent Judge at the Patent Trial  
12 and Appeal Board at the USPTO.

13 MS. MOEZIE: Hi, my name is Minna  
14 Moezie, I am a patent attorney in the Office of  
15 Policy and International Affairs, USPTO.

16 MS. FERRITER: Good afternoon, my name  
17 is Karin Ferriter, I am on detail from the Office  
18 of Policy and International Affairs to the Office  
19 of International Patent Cooperation, we're working  
20 on a number of different issues. So it's exciting  
21 to be here today. Thank you.

22 MS. EVANS: Good afternoon, my name is

1 Robin Evans and I am one of the Deputy  
2 Commissioners for Patents in Patents.

3 JUDGE HORNER: Thank you everybody. We  
4 will begin Session 4 hearing remarks from Ms.  
5 Juliana Reed from Biosimilars Forum. Ms. Reed.

6 MS. REED: Thank you. And thank you  
7 very much for this opportunity and for  
8 accommodating my crazy schedule, you guys are  
9 great. So thank you for that.

10 So the Biosimilars Forum, as I  
11 mentioned, we're very grateful for this  
12 opportunity, it's a very unique collaboration and  
13 the Biosimilars Forum being a very unique and new  
14 industry has a lot of recommendations that we will  
15 be formally sharing in more detail by February 6.

16 But a little bit about the Forum. The  
17 Forum is the Nonprofit Trade Association  
18 representing the companies in the U.S. developing  
19 biosimilars. And we also develop globally as  
20 well. So our companies are very familiar, not  
21 only with U.S. patent laws but also those around  
22 the world in highly regulated countries.



1           Our members include Biogen, Boehringer  
2     Ingelheim, Coherus Biosciences, Fresenius Kabi,  
3     Pfizer, Organon, which was the spin-off from  
4     Merck, Samsung Bioepis and Sandoz, which is part  
5     of Novartis. Our comments today represent the  
6     views of our members, all, as I mentioned,  
7     manufacture and market biosimilar products in the  
8     U.S. as well as other parts of the world.

9           I think it's also important to  
10    understand our members not only manufacture and  
11    develop biosimilars but generics, small molecule  
12    generics, in innovative drugs and therapies as  
13    well. So we have a very global perspective of  
14    this space and of the IP around it.

15          Biosimilars, as I think all of you know,  
16    have the potential to provide significant  
17    healthcare savings in the U.S. Without robust  
18    competition, innovator biologics will continue to  
19    represent approximately 40 percent of the total  
20    prescription drug spending while they represent  
21    only 4 percent of the medicines prescribed to  
22    patients.

1           While U.S. patients have the greatest  
2       access to innovative biologic medicines in the  
3       world, this has also resulted in the U.S. having  
4       the highest expenditures for these important  
5       medicines. Biosimilars has successfully provided  
6       competition to lower the cost of biological  
7       medicines not only here in the U.S. but again, as  
8       I mentioned, around the world.

9           The Forum greatly supports this  
10      collaboration initiative. In the goal to ensure  
11      that the patent system promotes research and  
12      development and protects key innovations while not  
13      incentivizing protecting or permitting activity  
14      that will improperly or unnecessarily delay access  
15      to low cost medicines such as biosims. We believe  
16      in robust and reliable patents. Such patents are  
17      needed, as we all know, to incentivize and protect  
18      the immense R&D that is essential to bringing  
19      lifesaving and life-changing medicines. And  
20      critically, we must bring innovation to impact the  
21      healthcare system for all Americans.

22           We're very pleased to see the PTO and

1 the FDA collaborating on this important work  
2 revising patents. We look forward to working with  
3 you to provide our comments and any expertise you  
4 need from industry, the biosimilars industry, on  
5 revisiting patent term extensions, clarifying  
6 skinny labels, which is very important for our new  
7 industry to receive clarity, examining patents  
8 thickets which have been profound and very  
9 detrimental to the launching of biosimilars in the  
10 U.S, improving procedures for obtaining a patent  
11 so that we also get robust and reliable patents,  
12 which is important. And conducting, as I  
13 mentioned earlier, with our members' global  
14 experience. We're very happy to work with you and  
15 to provide any information and experience we can  
16 as you conduct the comparative analysis of the  
17 U.S. patent system versus our experiences with  
18 other highly regulated countries around the world.

19 Biosimilar developers in this is a very  
20 critical challenge and costly challenge for our  
21 members and when we have to challenge an  
22 innovator's patent in order to be able to come to

1 the market. With new Medicare policies being  
2 implemented through the Inflation Reduction Act,  
3 challenging patents and getting the biosimilars to  
4 the market as early as possible after approval is  
5 critical. And the work this group is going to be  
6 doing is going to be critical to the long-term  
7 sustainability and success of the competitive  
8 lower cost biosimilar industry.

9 The initiatives the PTO collaboratives  
10 have outlined will result in improving patient  
11 quality in providing the much-needed clarity and  
12 guidance to the collective industry here present  
13 today. We support the initiative, we look forward  
14 to participating in the process. And we're  
15 looking as always to Biosimilar Forum looks for  
16 common-sense solutions that protect innovation but  
17 also promote competition.

18 So again, thank you very much for the  
19 opportunity to be here today, and we look forward  
20 to working with you however you need us to do  
21 that. Thank you.

22 JUDGE HORNER: Great. Thank you, Ms.

1       Reed, for your comments and for being here today.  
2       I'll open it up to the panel for questions. Go  
3       ahead.

4               MR. UNLU: You said you wanted somebody  
5       to clarify skinny labels. Can you say a little  
6       bit more about that and how would we do that?

7               MS. REED: Yes. And I also rely on my  
8       real patent expert to help me answer this. But  
9       what I think what we're looking for on the skinny  
10      labels is the ability and how do we carve out and  
11      continue to carve out so that we can bring a  
12      biosimilar to the market for less indications or  
13      other indications that may still be patent  
14      protected.

15              So and I think you know, I mean and we  
16      work with your group very closely, it's very  
17      important as we do our education and position with  
18      package inserts and everything else to have that  
19      really good clarity both from the FDA and the  
20      skinny label, but also the PTO. So that's where  
21      we're looking for so that we can again develop and  
22      bring a product to market as quickly as possible.

1 MR. UNLU: Thank you.

2 MS. REED: No, thank you.

3 JUDGE HORNER: I have a question. Can  
4 you describe sort of the size, typical size of  
5 member companies within your organization? And do  
6 they use the Patent Trial and Appeal Board  
7 proceedings at all?

8 MS. REED: Yeah.

9 JUDGE HORNER: Has that been an  
10 effective tool for them or are there ways to make  
11 it more effective?

12 MS. REED: So the preference is to go  
13 through PTAB and IPR and deal with that. One of  
14 the key things, so going back to the first part of  
15 your question, the size of our companies and  
16 members. As you can imagine, Pfizer being one of  
17 the largest pharmaceutical companies in the world  
18 down to Coherus Biosciences which is a small  
19 startup, biotech startup in Redwood City, the Bay  
20 Area. And they only have a couple products. So I  
21 think that's really key.

22 But the PTAB and IPR is very important.

1 But you also have to look at the innovator side of  
2 this. And what's really important to us is when  
3 we see patents that give significant patent  
4 estates that are created, unfortunately created  
5 just to prohibit competition. And this is  
6 prevalent in the biologic space. Where there's  
7 products that are biosimilars that are approved  
8 and on the shelf for another 10 years because of a  
9 submarine patent. And the innovator product has  
10 been on the marketplace for over 20 years so it  
11 has no competition, submarine patent comes up, it  
12 has another 10 years of market monopoly. So what  
13 is so important and we expect to see and need to  
14 see is ongoing. The litigation cost for over 100  
15 patents is cost prohibitive to development of a  
16 biosimilar. Development of a biosimilar right now  
17 with the FDA is I think six to nine years and it's  
18 rounding up to close to \$200 million. So it's not  
19 anything near a small molecule generic. And the  
20 patent estates is another \$100 million, it could  
21 be because that's through PTAB, right? It's at  
22 least a million dollars per patent so it depends

1 on the patent dance and where we're going to go.

2 And I could talk all day so my apologies.

3 But I think we're also looking for and  
4 want to continue to educate in is the need.  
5 Because of the prohibitive cost of the patent  
6 estates and the amount of time and money it could  
7 take biosimilar, regardless of the size of the  
8 company. So Pfizer, Coherus, Fresenius Kabi, all  
9 of our members face the patent challenges and the  
10 cost.

11 Patent settlements are very important to  
12 the biologic biosimilar space. It gives us timely  
13 and actionable launch dates. It's going to be  
14 very important moving forward under the CMF  
15 Inflation Reduction Act because if an innovator  
16 wants to have a delay in any pricing negotiations,  
17 biosimilar must launch. So it's a complicated  
18 answer to a complicated question.

19 But biosimilar patents and challenges  
20 and what we need to do, this collaborative is so  
21 important. Because one, clarity on what the  
22 patent term extension, clarity on what's the real



1 innovation so that we can start to see patent  
2 estates protecting innovation versus market access  
3 and competition. That's really important to us.

4 And then our goal is to shorten the  
5 amount of time to develop a biosimilar in the  
6 future. We're very grateful for FDA to work on  
7 that with us. But also to shorten the amount of  
8 time and money it costs for a patent challenge.  
9 And then I think you'll see that we'll be able to  
10 get more biosimilars out on the marketplace  
11 faster.

12 JUDGE HORNER: Thank you.

13 MS. REED: Sorry to take all the time.

14 JUDGE HORNER: No problem. Okay, we'll  
15 go on. Thank you for your comments.

16 MS. REED: Yeah, thank you.

17 JUDGE HORNER: We'll move on to our next  
18 speaker, Mr. David Korn from PhRMA.

19 MR. KORN: Thank you for holding this  
20 meeting and inviting views of the public. I'm  
21 David Korn, Vice President IP and Law at the  
22 Pharmaceutical Research and Manufactures of

1 America.

2           PhRMA represents leading innovative  
3 biopharmaceutical companies whose mission is to  
4 research and develop new and improved medicines  
5 for patients. Intellectual property provides  
6 critical incentives for biopharmaceutical  
7 innovation given the unique nature of the  
8 biopharmaceutical research and development or R&D  
9 process, which is lengthy, costly, and uncertain.  
10 It takes 10 to 15 years and costs on average \$2.6  
11 billion to develop a new medicine. In 2021 PhRMA  
12 members alone invested more than \$100 billion in  
13 researching and developing medicines. IP  
14 protection supports such continued future  
15 innovation in the long term.

16           PhRMA supports the important role of  
17 generic and biosimilar products for patients. The  
18 natural evolution of medicines is that after an  
19 innovator undertakes the time- consuming and  
20 expense of development process and obtains FDA  
21 approval, it enjoys an appropriate period of IP  
22 protections, following which a generic or

1        biosimilar version may become available for  
2        patients. This is the cycle that Hatch-Waxman and  
3        the BPCIA contemplated for generics and  
4        biosimilars.

5                Hatch-Waxman has fostered competition  
6        through the timely entry of generics. Today 90  
7        percent of all prescriptions for drugs are filled  
8        with generic products and the biosimilar market  
9        continues to grow. Both have led to cost savings.  
10       Post-approval innovation such as new dosage forms  
11       and routes of administration is a critical part of  
12       pharmaceutical development, producing important  
13       treatment benefits for patients. R&D does not  
14       stop and should not stop with initial FDA approval  
15       of a medicine. A medicine's safety and  
16       effectiveness are not determined solely by its  
17       active ingredients. And its therapeutic  
18       usefulness is not limited to its first approved  
19       disease.

20               Post-approval changes can improve a  
21       medicine's tolerability, effectiveness, adherence,  
22       or convenience, and support its approval for new

1 diseases in patients with unmet medical needs.  
2 Such post-approval advances benefit patients and  
3 the public health and should be incentivized by  
4 the patent system rather than discouraged.

5 U.S. continuation practice helps provide  
6 the incentive for innovators to develop the many  
7 types of patentable inventions at different stages  
8 of a product's life. The availability of  
9 continuation applications helps foster the patent  
10 system's goal of promoting innovation and earlier  
11 disclosure in the original application of the  
12 underlying research that resulted in the  
13 innovation.

14 The original application provides the  
15 public and competitors with notice of the  
16 applicant's inventions and thus what can be  
17 claimed in its continuation applications. This  
18 framework is fair and strikes the right balance  
19 between protecting innovators and providing  
20 society of its benefits. Such a system  
21 differentiates the patent system from other means  
22 of IP protection such as trade secret protection

1 by rewarding innovators who disclose their  
2 inventions.

3 Limiting continuing practice would not  
4 promote innovation and progress in science.  
5 Inventors would be disincentivized from robustly  
6 disclosing their inventions if there were  
7 uncertainty around whether they could receive the  
8 benefit of patent protection for the full scope of  
9 its disclosed innovation.

10 Indeed, the negative rhetoric regarding  
11 patents on post-approval advances more broadly,  
12 including on manufacturing process patents, is  
13 concerning. Providing IP protection for such  
14 innovation does not negatively affect access to  
15 generics or biosimilars. Once IP protections on  
16 an original drug product have ended and provided  
17 there are no safety issues, copies of that product  
18 may be approved. Healthcare providers and payers  
19 can then decide whether clinical benefits offered  
20 by the improved branded products are more  
21 important than the cost savings available through  
22 use of less expensive generics or biosimilars.

1           And generic or biosimilar applicants can  
2       often design around certain patents and carve  
3       protected conditions of use out of their labeling,  
4       allowing generic or biosimilar products to enter  
5       the market prior to the expiration of all patents  
6       or exclusivities covering a product.

7           We've seen letters that suggest more  
8       direct collaboration between FDA and USPTO is  
9       warranted due to concerns about potential  
10      inconsistent statements made to the agencies by  
11      pharmaceutical innovators. We've also heard  
12      theoretical concerns about manufacturing process  
13      patents. Proponents of the inconsistent statement  
14      narrative cite a single drug case, Belcher v.  
15      Hospira. One case is hardly indicative of a  
16      systemic problem. And in that case the court  
17      imposed a severe penalty, the patent was held  
18      unenforceable.

19           Indeed, there have been 4,696  
20      Hatch-Waxman cases file in U.S. District Courts  
21      between 2008 and 2022 and we have seen no evidence  
22      of a wide-spread problem of inconsistent

1 statements to FDA and USPTO.

2           Moreover, increased information sharing  
3 across agencies raises confidentiality concerns.  
4 The agencies have different practices for handling  
5 confidential information. The USPTO's general  
6 position is that information material to  
7 patentability must be disclosed to the public.  
8 Whereas FDA is subject to specific statutory  
9 restrictions on sharing proprietary information.

10           Accordingly, PhRMA is concerned that  
11 materials that are confidential at FDA will not be  
12 treated as confidential by USPTO. Any policy  
13 changes to the U.S. patent system, including  
14 increased collaboration between these two  
15 agencies, should be based on evidence of the need  
16 for the change. This is especially the case when  
17 the collaboration could put trade secrets and  
18 confidential commercial information at risk.

19           Similarly, PhRMA's aware that there are  
20 alleged concerns about the number of patents per  
21 product. Reports on this topic are inaccurate and  
22 the validity of the numbers of patents and

1       protections reported have been called into  
2       question. Further, this is not a useful measure  
3       for policymaking. Many of society's most  
4       innovative products embody numerous inventions  
5       protected by multiple patents. The U.S.patent  
6       system should celebrate and encourage such a  
7       complex innovation.

8               The United States has historically been  
9       a science and technology innovation leader in the  
10       world. To maintain this standing in the 21st  
11       Century policy leaders must ensure that our laws  
12       continue to support innovation. PhRMA plans to  
13       submit written comments and looks forward to  
14       working with the agencies on policy issues to  
15       improve the biopharmaceutical ecosystem. We need  
16       a policy and regulatory framework that fosters the  
17       continued innovation necessary to address the  
18       world's most challenging diseases.

19              JUDGE HORNER: Thank you, Mr. Korn. I  
20       will submit that to the panel for any questions.  
21       No questions?

22              I have one question. Could you go into



1 a little bit more detail, you were talking about  
2 continuing R&D post approval. Can you go into a  
3 little more detail on what kinds of R&D happen  
4 post-approval and if you have information on sort  
5 of the breakdown of the statistics of, you may not  
6 have this, I understand, but what percentage of  
7 your investments, your member companies  
8 investments in R&D go into post-approval R&D  
9 versus pre-approval R&D? What kind of things  
10 happen after approval?

11 MR. KORN: I don't have those  
12 statistics, and we couldn't address the question  
13 in the comments. But it's both from the technical  
14 perspective of improving the product and how it's  
15 presented to patients, how it's delivered, as well  
16 as the diseases. There could be new diseases, new  
17 ways of treating a particular disease, new patient  
18 populations. And all of this is happening after  
19 the original approval.

20 JUDGE HORNER: Yes. Karin.

21 MS. FERRITER: Thank you very much for  
22 your comments and for testifying today. A lot of

1 people really appreciate the Orange Book because  
2 it provides a listing of the drug products and  
3 method of use part of patents that are relevant to  
4 a specific drug. And it's really a useful  
5 reference tool. However, it doesn't list, as you  
6 know, method of manufacturing patents. Could you,  
7 for the benefit of our analysis, talk a little bit  
8 about why it doesn't and just explain why or  
9 whether it should or should not in the future be  
10 changed to list such patents?

11 MR. KORN: Thanks for the question. So  
12 when Congress was looking at developing  
13 Hatch-Waxman the question was what patents are  
14 relevant as far as the particular product. And  
15 manufacturing is not something where there's a  
16 standard that a generic company needs to produce  
17 the same product in the same way. There's the  
18 same active ingredient standards, bioequivalent  
19 standards, same labeling, but not same  
20 manufacturing process.

21 So it is something where generics are  
22 free to use different manufacturing processes to

1       come up with the same bioequivalent product in the  
2       end.

3               MS. FERRITER:  If I can just follow up a  
4       little bit.  So we have the Orange Book process  
5       for drugs that we've just described, and then the  
6       Purple Book processes evolved to be quite  
7       different.  Can you at a super high level describe  
8       whether we're in a good place for the Purple Book  
9       or should it be changed to be more like the Orange  
10      Book, or is it because of the importance of method  
11      of manufacturing processes being different that we  
12      probably will continue to have different  
13      procedures?

14             MR. KORN:  I think manufacturing process  
15      patents are an element of it, and the nature of  
16      the process in the BPCIA for patents, it's focused  
17      on patents relevant to the biosimilar, not patents  
18      relevant to the innovative product.  And the  
19      Purple Book now reflects that whole process  
20      overall and the development of biosimilars.

21             MR. RITTERBECK:  Thanks for your  
22      comments.  I just had one point that I wanted to

1       clarify. In your comments you mention that any  
2       policy changes, including collaboration between  
3       the PTO and the FDA need to be based on evidence  
4       for, you know, needing a change. I just want to  
5       clarify, is it PhRMA's position that there is no  
6       evidence that there's a need for change as it  
7       relates to the collaboration between the PTO and  
8       FDA, vis-à-vis drug pricing and competition?

9               MR. KORN: I think it's up to the  
10       policymakers on that. There certainly have been  
11       people who have called for a degree of change and  
12       the office, the two agencies, are already working  
13       on training and the like. We don't see a need to  
14       have further policy changes, but we can address  
15       that more fully too. Thank you.

16              JUDGE HORNER: Thank you, Mr. Korn, for  
17       your comments. We'll move on to our next speaker.  
18       Professor Liza Vertinsky, University of Maryland  
19       Francis King Carey School of Law.

20              PROF. VERINSKY: Thanks for this  
21       opportunity to speak with you today. The USPTO  
22       and FDA have announced a joint initiative designed

1       to ensure that "Our innovation system strikes the  
2       appropriate balance encouraging meaningful  
3       innovation in drug development while supporting a  
4       competitive marketplace that can promote greater  
5       access to medicines for American families."

6               I'd like to suggest that as part of  
7       achieving this balance USPTO and FDA have a  
8       crucial role to play in ensuring that public  
9       funding and public participation in the innovation  
10      process is given greater consideration.

11              My remarks today focus on the  
12      opportunities to augment the public role and the  
13      initiatives included in Director Vidal's July 6  
14      letter.

15              Section 1(d) of the letter address the  
16      issue of disclosure. The USPTO could do a lot  
17      more to incentivize and enforce the disclosure and  
18      reporting obligations of patent applicants who  
19      have benefitted from federal funding of research  
20      that's led to their inventions.

21              Doing so would serve the public interest  
22      by promoting transparency and accountability in

1     the development and use of publicly funded  
2     inventions. It's also allowing the government to  
3     more easily determine whether and when it might  
4     need to exercise its retained rights to ensure  
5     reasonable access to the patented inventions.

6             The Bayh-Dole Act allows recipients of  
7     federal funding to receive title to inventions  
8     developed using federal funds. But in return, the  
9     Act grants the government automatic non-exclusive  
10    fully paid-up licenses to inventions developed  
11    using federal funding. As well as the right to  
12    use these inventions under specified  
13    circumstances.

14            In addition, the Act imposes specific  
15    disclosure and reporting obligations on recipients  
16    of federal funding regarding the rights retained  
17    by the government in the inventions to which they  
18    have retained title. These obligations include a  
19    duty to disclose the inventions to the federal  
20    funding agency within a reasonable time and to  
21    make periodic reports on how the inventions are  
22    being utilized.

1           But more importantly for our current  
2       discussion today, the Act requires recipients of  
3       federal research funds to include a statement in  
4       their patent applications that their inventions  
5       were made with government support and they're  
6       subject to government retained rights.

7           Enforcing patent applicant's obligations  
8       to make these statements and to do so accurately  
9       is critically important because it could create  
10      opportunities for third-party oversight that can  
11      serve as additional checks on improper use of  
12      patents covering government funded inventions.

13          The Act's disclosure and reporting  
14      requirements and reserve government rights are  
15      important public policy levers designed to ensure  
16      the appropriate balance of public and private  
17      interests in inventions developed with public  
18      funds.

19          However, research has shown that patent  
20      applicants regularly under report government  
21      rights in federally funded inventions and that  
22      government efforts to enforce these reporting

1 obligations are lax at best. A recent salient  
2 example involves Moderna's failure to disclose  
3 federal funding in patents on the technology  
4 underlying its COVID vaccine. Moderna's COVID  
5 vaccine received substantial funding from both the  
6 NIH and BARDA and yet Moderna has failed to  
7 disclose government funding in its patent  
8 applications and patents. Accurate disclosure,  
9 again, is crucial because, as I already mentioned,  
10 there are important public rights attached to  
11 these inventions.

12 While the federal funding agencies have  
13 the primary responsibility for the enforcement of  
14 the Bayh-Dole Act disclosure and reporting  
15 obligations, I think the USPTO and FDA can play  
16 important supportive roles in enhancing compliance  
17 and improving the accuracy of disclosure.

18 To give you a few examples or ideas,  
19 Section 1(d) of the letter specifically mentions  
20 exploring initiatives to require patent applicants  
21 to provide relevant information to USPTO that has  
22 been submitted to other agencies and to remind



1 patent applicants of their disclosure obligations  
2 and the ramifications of failing to disclose  
3 required information.

4 As part of this effort the USPTO could  
5 include specific requirements for the reporting of  
6 federal funding and attach meaningful consequences  
7 to the failure to report. Reporting federal  
8 funding could be regarded as information material  
9 for patentability, for example, and subject to the  
10 same duty to disclose as other material  
11 information. Delays in disclosure should be  
12 penalized where the applicant should have known at  
13 the time of filing that the admissions were  
14 subject to Bayh-Dole requirements in order to  
15 avoid strategic behavior by patent applicants.

16 The USPTO should also consider ways to  
17 facilitate greater public access to information  
18 about the public funding, particularly those  
19 covering inventions in the biomedical areas.

20 Section 2 of the letter explores ways of  
21 improving procedures for obtaining patents.  
22 Efforts to enhance information disclosure

1 statements discussed in Section 2(d) along with  
2 the development of resources such as the design of  
3 an amalgamated tool for patent examiners, could  
4 also include required disclosure of public funding  
5 along with the identification of prior art. And  
6 in addition, patent examiners ought to receive  
7 more time and resources for the examination of  
8 patent applications covered by biomedical  
9 inventions so they can investigate effectively  
10 compliance with government funding disclosure  
11 obligations.

12 Finally, in addition to the focus on  
13 enforcing existing Bayh-Dole obligations, the FDA  
14 and the USPTO have an important role to play in  
15 developing best practices for awarding patents and  
16 regulatory exclusivities where public/private  
17 partnerships are involved. Effective  
18 collaboration requires a balanced approach to  
19 patenting and data sharing practices that  
20 incorporates both private incentives to  
21 participate and public interest and access to the  
22 knowledge generated in the products that results.

1                   When developing best practices the  
2           Bayh-Dole obligations should be considered as  
3           minimum requirements. They should continue to be  
4           incorporated in future federal funding agreements,  
5           including those involving high profile  
6           public/private partnerships such as ARPA.

7                   Thanks so much for your time.

8                   JUDGE HORNER: Thank you Professor  
9           Vertinsky. Do we have any questions from the  
10          panel? Robin.

11                  MS. EVANS: I have one. Thank you so  
12          much for your comments. You mentioned that the  
13          USPTO could incentivize making such disclosure  
14          statements. I was wondering if you had any other  
15          comments or what those incentives you think might  
16          be?

17                  PROF. VERTINSKY: And I'm currently  
18          working on some other ideas but the one that I  
19          mentioned today was it would require sort of a  
20          change in regulations but to treat disclosures of  
21          public funding in ways similar to the ways we  
22          treat disclosure of material information for

1 patentability, right. And so if you don't  
2 disclose information material to patentability  
3 there's significant consequences to that. Not so  
4 much with failure to disclose federal funding,  
5 that's typically left to the federal funding  
6 agencies, but that sort of oversight hasn't worked  
7 well so far.

8 MS. EVANS: Thank you.

9 MS. FERRITER: And thank you very much  
10 for coming here today and talking about this  
11 really important topic. There has been a lot of  
12 interest as you've noted in this aspect of  
13 Bayh-Dole. Because these disclosures, when we do  
14 receive them, are part of the published patent  
15 application, I'm wondering how often you as a  
16 researcher try to analyze that data and is your  
17 ability to use the patent database sufficient for  
18 your work?

19 PROF. VERTINSKY: So there's actually  
20 been researchers, Heidi Williams and her co-op is  
21 for one, I've referenced those in my submitted  
22 remarks. And they describe in their paper the

1       difficulties of trying to match and identify the  
2       public funding to particular applications.

3               And just a little bit further along  
4       that, something that they don't include, they  
5       discuss their methodology and their work really  
6       well I think. But one of the reasons I think  
7       there's an opportunity for the USPTO and the FDA  
8       to work together is the FDA works with companies  
9       on a repeated basis over long periods of time. So  
10      they have sort of an understanding of the  
11      different actors, public and private involved.  
12      And they're also often involved in these  
13      public/private partnerships as well. And so  
14      there's information that they might have about the  
15      public funding that might be useful in this cross  
16      fertilization. And again, that's not something  
17      that researchers could access or map easily onto  
18      without help.

19             MS. DAVIS: Thank you very much for your  
20      presentation. Could you talk a little bit more  
21      about the suggestion that we develop best  
22      practices in the context of awarding regulatory

1       exclusivities for considering whether  
2       public/private partnerships were involved. We  
3       already consider under the law whether a relevant  
4       clinical investigation was conducted or sponsored  
5       by the applicant. Do you have thoughts for  
6       modification to current practice, or is it more  
7       making best practices more transparent to  
8       stakeholders or if you can give any further  
9       context on what you were thinking along those  
10      lines, that would be helpful.

11               PROF. VERTINSKY: So the area that I  
12      have looked at most is on the contracting side.  
13      And I know that the FDA is not directly involved  
14      in what those contracts between the public and  
15      private actors look like. So what I was sort of  
16      suggesting is in this sort of whole of government  
17      approach, which I know has been a theme of these  
18      hearings, that you're the knowledge, you have sort  
19      of the combined knowledge experts of this process  
20      and have important roles to play in for example  
21      maybe pushing back against this tendency towards  
22      using other transactions authority to reduce the

1 public rights in the products that are being  
2 developed.

3 And so I see the role more as this whole  
4 of government approach in which you have the  
5 knowledge to discuss with the people who are  
6 writing the contracts about the importance of, for  
7 example keeping the Bayh-Dole Act in place because  
8 of its role in maintaining that balance. So it's  
9 an indirect role. There may be other roles but  
10 I'm confined by, I serve my best in transactional  
11 IP, so that's what I know more about.

12 JUDGE HORNER: Thank you for your  
13 comments today and for taking the time to be here.

14 We're going to move to our next speaker,  
15 and he is virtual. Dr. Sean Tu from West Virginia  
16 University College of Law. Dr. Tu.

17 DR. TU: All right. Can you hear me?

18 JUDGE HORNER: We can hear you and we  
19 should be able to see you in just a moment. We  
20 see you now. Please go ahead.

21 DR. TU: So I wanted to thank the PTO  
22 and FDA for organizing this event. We have some

1 really smart people here who have thought long and  
2 hard about these issues surrounding patenting in  
3 the pharmaceutical area.

4 I am an academic who has been studying  
5 the patent system for about two decades at the  
6 West Virginia University College of Law. So I  
7 wanted to start by saying that I love the patent  
8 system and I think it's made the U.S. stand out as  
9 one of the most innovative countries in the world.

10 The patent system was designed to reward  
11 and inspire innovation, and when it works it works  
12 really well. The problem for me is that I believe  
13 that the patent system is being manipulated to  
14 extend monopoly power and to unethically  
15 prioritize the profits of the few over the  
16 well-being of the community, including those  
17 patients and those who are suffering from  
18 life-threatening diseases.

19 So I think it's clear that one of the  
20 most effective ways to lower high drug prices is  
21 to let the free market do its work and lower drug  
22 costs. When generics and biosimilar competitors



1       enter the market, market prices go down. However,  
2       when they are unreasonably prevented from entering  
3       the market multiple parties are harmed. Patients  
4       end up having to pay higher prices and face worse  
5       health outcomes, employers end up paying higher  
6       insurance premiums, and taxpayers shell out more  
7       to cover higher Medicare and Medicaid costs.

8               Although the patent system was designed  
9       to allow inventors to profit from their  
10       inventions, this type of drawn- out profiteering  
11       is really not what the patent system was created  
12       to do. So I'm going to focus on just one area  
13       where I think gamesmanship is occurring, namely  
14       the creation of patent thickets and continuation  
15       practice.

16              So patent thickets are just a whole lot  
17       of patents connected to the same product. Generic  
18       and biosimilar firms must challenge scores of  
19       non-patentable distinct patents before getting to  
20       market. This may be why firms settle instead of  
21       litigating to a final decision.

22              Additionally, IPRs don't work well

1     because IPRs are instituted on a patent-by-patent  
2     basis which is maybe why we see fewer firms using  
3     IPRs compared to a decade ago. Thus competitors  
4     really face an uphill battle in terms of time,  
5     cost, and clarity even when going after what some  
6     would consider weak patents. Our continuation  
7     patents, or Cons, are a key component of patent  
8     thickets because they allow drug companies to  
9     build large patent portfolios comprised of lower  
10    quality patents. Cons are typically narrower than  
11    their parent applications and are usually linked  
12    to each other via terminal disclaimers.

13               Cons are easier to file and can move  
14    through the patent system quicker than a typical  
15    application because one, they're usually were  
16    given to the same examiner so that examiner should  
17    already be familiar with the invention and the  
18    prior art. And two, there are avenues for  
19    traversal that are not present in other  
20    applications, namely terminal disclaimers.

21               Finally, the PTO may be unwittingly  
22    helping to create these patent thickets by

1        incentivizing examiners to handle Cons. Patent  
2        examiners love Cons because it allows them to meet  
3        their hourly, or their quarterly quotas with  
4        relatively minimal effort, all right?

5                So my research has shown that there's  
6        been an overall increase in the patent intensity  
7        in the pharmaceutical field. So from 2001 to 2019  
8        there has been a three-fold increase in the number  
9        of patents associated with each active ingredient  
10       listed in the Orange Book. And that's public data  
11       from Heidi Williams in her NBER data.

12               Correspondingly there's been a six-fold  
13       increase in the number of use codes that is  
14       associated with each active ingredient, from about  
15       1,200 to over 8,000. So pharmaceutical firms  
16       really seem to be relying more and more on these  
17       lower quality patents to protect their products.

18               To examine the role of Cons in these  
19       thickets I analyzed every patent that was issued  
20       since 1980, about 7 million patents, every  
21       litigated patent since 1980, about 46,000 patents,  
22       every Orange Book patent, and every litigated

1 Orange Book patent since 1984. We find that the  
2 pharmaceutical industry relies on Cons more than  
3 any other industry. You know, Cons, as I said  
4 earlier, that Cons are used by industries, other  
5 industries, and that's true. However no one  
6 litigates Cons like the pharmaceutical industry.  
7 55 percent of all litigated Orange Book patents  
8 are Cons. I note that very few industries rely on  
9 Cons. In fact the top 15 CPC codes account for 46  
10 percent of all filed Cons and 55 percent of all  
11 litigated Cons. These correspond to the software,  
12 semiconductor, and pharmaceutical industries.

13           So in addition to that I've looked at  
14 the prosecution histories of all of these Orange  
15 Book patents, about 4,000 patents, and I found  
16 that Cons really don't disclose very much that's  
17 new but are simply narrower versions of the  
18 original patent. I say this because I've looked  
19 at the number of words in the claims for each  
20 independent claim in the patent. And you can see  
21 that with each increasing generation, the number  
22 of words in each claim increases pretty

1       dramatically when you reach like the fifth  
2       generation, which is the great, great, great,  
3       great grandchild of the original patent.

4               Unsurprisingly, there's also a linear  
5       decrease in the amount and type of rejections you  
6       get as you move down the Con chain. So when you  
7       have more and more generations you get fewer and  
8       fewer 102, 103, 112(a) and 112(b) rejections. The  
9       only type of rejection that increases is the ODP  
10      rejection, and that goes up from 20 percent to 70  
11      percent as you move up the chain.

12              These data argue that with more Cons,  
13      that conversation between the examiner and  
14      applicant is less and less useful. Likely because  
15      there's really no change in claims scope between  
16      the second and fifth generation of the patent.

17              So what do we do about this? Cons are  
18      not a new problem, right? However, previous  
19      attempts to deter Cons have really been met with  
20      heavy industry resistance. There are several  
21      possible solutions that I've written about that  
22      may not require conventional intervention. Some

1       may require it, depending on how you interpret the  
2       law.

3               First the PTO should require applicants  
4       to identify their patents as potential Orange Book  
5       patents so that the PTO could give them to a  
6       special art unit that uses team examination with  
7       added support. We know these patents are  
8       important and thus should be given detailed review  
9       necessary to grant high quality patents. This  
10       might also help with flagging these patents for  
11       patient inputs as they may have a harder time kind  
12       of defining which patents are relevant.

13              Second, the PTO and FDA should  
14       collaborate to verify the information that's  
15       submitted to the FDA for Orange Book listing is  
16       correct.

17              Third, the PTO should increase the fees  
18       associated with serial Cons. Just like we  
19       increased maintenance fees from years 3 to 7 to  
20       11, we should increase the fees associated with  
21       the second, third, fourth, and subsequent  
22       generation Cons.

1                   Fourth, the PTO should pay closer  
2                   attention to these large patent families that  
3                   would require significant numbers of ODP  
4                   rejections. As part of the solution I think the  
5                   PTO could abolish the use of terminal disclaimers  
6                   and require applicants to explain how their Cons  
7                   are patentably distinct from the claims that are  
8                   already present in the family.

9                   Fifth, the PTO could allow IPR  
10                  challenges, not to apply on a patent-by-patent  
11                  basis but via the whole Con family.

12                  And finally, the PTO could limit the  
13                  number of Cons to just two and limit it to  
14                  broadening Cons to two years after the notice of  
15                  allowance of the original patent.

16                  JUDGE HORNER: Thank you, Dr. Tu. Going  
17                  to open it up for panel questions. Robin.

18                  MS. EVANS: Yes, thank you. Thank you,  
19                  Dr. Tu. I was interested in hearing, to see if  
20                  you could tell us a little bit more about the team  
21                  review and how you think that would help the  
22                  process.

1                   DR. TU: Yeah. So I wrote a paper  
2 recently with Mark Lemley about this, published in  
3 the Washington Law Review. You know, Lisa Lett  
4 from Stanford has also written about this. And  
5 they did this actually in the rubric of food  
6 inspections in New York. And they found that when  
7 you get two food inspectors instead of just one  
8 food inspector and they work together, you get  
9 actually better quality examination of restaurants  
10 and more consistent review of restaurants who may  
11 or may not pass that inspection.

12                   And I think we could have a similar  
13 system where we could have two or three examiners,  
14 one of them, you know, very few examiners right  
15 now have medical degrees or are trained in both  
16 examining FDA information and medical information.  
17 I can imagine a system where if you have at least  
18 one person in that team, you would have better  
19 examination.

20                   I think everybody wants higher quality  
21 patents. And this I think is one way we can get  
22 to that without really having to just simply add



1       time for examiners. To be honest, I don't think  
2       adding time for examiners is going to help all  
3       that much. I've seen that when examiners are  
4       given Cons, like what do they do, they cut and  
5       paste from one family to another. So they have  
6       more time but they're not using that time. And it  
7       makes sense the way our count system is based  
8       really on quantity and not so much quality. And,  
9       you know, like it makes sense that you would give  
10      similar rejections to cases that look pretty much  
11      identical.

12                So I don't blame them for doing what  
13      they do right now, but I think having more input,  
14      more perspective, would get us better examinations  
15      and stronger patents in the long run.

16                JUDGE HORNER: Marianne.

17                MS. TERROT: Hi, Professor Tu. I have a  
18      follow up question on this idea of flagging  
19      potentially Orange Book listable patent  
20      applications. Were you envisioning, what would  
21      you consider needing to be flagged, like that  
22      there is an active ingredient that's already in an

1 approved NDA or flagging that there's a pending  
2 NDA -- how early? Because otherwise some art  
3 units, I think everything is potentially --

4 DR. TU: Well first of all I've done the  
5 analysis and, you know, when it comes to Orange  
6 Book patents it's mainly 1611 and 1612 I think  
7 have like the lion's share of Orange Book patents.  
8 1643 and 1644 have the lion's share of biological  
9 patents. So it's already kind of self-selecting.

10 But the way I imagine it is the  
11 applicant, if they submit the patent as filed, if  
12 those claims were allowed, if they were going to  
13 file it in the Orange Book, it would be  
14 self-identified by the applicant. If the claims  
15 as published or as submitted would be filed in the  
16 Orange Book then it should go to that argument.

17 MS. TERROT: You mean if there is an  
18 approved product that those claims as filed, if  
19 the product is already approved then.

20 DR. TU: No, that would be an ex-post  
21 kind of review. You would want it an anti-kind of  
22 review. So if the claim would go to a product, it

1       would have to be much earlier, right? So again it  
2       would be kind of a thought experiment for the  
3       applicant, but I don't think it would flood the  
4       system with this art unit going, you know, having  
5       a ton of patent applications go to it.

6               JUDGE HORNER: All right. Thank you,  
7       Dr. Tu, for your remarks and for your suggestions.  
8       We're going to move to our next speaker, Mrs.  
9       Sarah Bourland, Patients for Affordable Drugs.

10              MRS. BOURLAND: Thank you for inviting  
11       input on USPTO and FDA joint initiatives. My name  
12       is Sarah Kaminer Bourland, and I represent  
13       Patients for Affordable Drugs Now, the only  
14       national patient group focused exclusively on  
15       policies to lower drug prices.

16              We are bipartisan and do not accept  
17       funding from any organizations that profit from  
18       the development or distribution of prescription  
19       drugs. I lead PFAD's policy and legislative work  
20       as Legislative Director. I am also a Registered  
21       Nurse. And as a nurse I've spent much of my  
22       career treating patients for illnesses that could

1     have been prevented by better, more effective  
2     policy, including those that promote lower drug  
3     prices.

4             The FDA and the USPTO have missions that  
5     directly impact the health of patients and  
6     communities. The FDA promotes safety and protects  
7     consumers by regulating and granting market  
8     exclusivity to pharmaceutical products. And the  
9     USPTO facilitates commerce and fosters innovation  
10    by granting patents.

11            Since both agencies confirm monopoly  
12    rights you play a critical role in competition and  
13    in the prices paid by the millions of people who  
14    take medications every day. For this reason we  
15    welcome the collaboration between your agencies  
16    and urge you to center patient and consumer  
17    interest in this work.

18            Today I will discuss three key  
19    initiatives we hope your agencies will continue to  
20    collaborate on in order to better facilitate  
21    competition and lower prescription drug prices.

22            First, it's important that your agencies

1 work together to alter incentives and increase  
2 oversight of data provided by drug corporations.  
3 The current system encourages brand name companies  
4 to present different and often conflicting  
5 information to the FDA and USPTO about the same  
6 drug.

7           Today drug companies are incentivized to  
8 make false statements or omit statements to the  
9 USPTO about a drug being novel or non-obvious  
10 enough to patent while simultaneously telling the  
11 FDA the drug is so similar to a product on the  
12 market that additional clinical tests are  
13 unnecessary.

14           Gaining approval of these two agencies  
15 in this deceptive manner enables brand name drug  
16 companies to engage in product hopping behavior, a  
17 strategy used to switch patients from an older  
18 medication to a newer version of the same product  
19 that has longer monopoly protection. Product  
20 hopping blocks generic competition, keeps prices  
21 high, and undermines true innovation. We  
22 submitted an example of this phenomenon in our

1       written comments.

2               Increased oversight, communication, and  
3       collaboration between your agencies is integral to  
4       cracking down on behaviors like this. We welcomed  
5       USPTO's commitment last year to the FDA to examine  
6       the consistency of statements provided to the two  
7       agencies and to explore initiatives that would  
8       require applicants to provide to the USPTO  
9       relevant information that was submitted to other  
10      agencies about the invention under consideration.

11              Second, we believe that prioritizing  
12      quality over quantity in the examination and  
13      awarding of patents would contribute meaningfully  
14      to improved health for patients. Too often  
15      patients in our community cannot afford their  
16      needed medications because a pharmaceutical  
17      company has obtained an excessive amount of  
18      patents in order to block competitors and maintain  
19      their monopoly prices.

20              According to a recent investigation by  
21      the House Oversight Committee, the 12 costliest  
22      products to Medicare are protected by over 600

1 patents designed to inflate those drugs from  
2 competition that could lower prices and save  
3 patients and taxpayers money. A noteworthy  
4 example is AbbVie's filing of 165 patent  
5 applications on it's block-buster cancer drug,  
6 IMBRUVICA, with more than half filed after FDA  
7 approval.

8 Opponents of reform point to litigation  
9 records to say that patent thickets are not  
10 actually thwarting generic entry. Secondary  
11 patents do not need to actually be asserted to  
12 deter competition. The mere presence of excess  
13 patents is often enough to deter a company from  
14 pursuing the development of a competitor at all.

15 Thorough scrutiny of the multitudes of  
16 patent applications that come before the USPTO is  
17 essential to ensure the patent system promotes  
18 innovation effectively and equitably. We realize  
19 this creates a significant administrative burden  
20 for the agency and that patent examiners who carry  
21 out the task of scrutinizing these applications.  
22 But prioritizing the quality of examination over

1 volume of patents is the only way to ensure the  
2 patent system incentivizes the creation of novel  
3 and non-obvious inventions.

4 To facilitate this we agree that patent  
5 examiners should be provided with additional time,  
6 education, and resources as necessary for  
7 reviewing the inherently complex pharmaceutical  
8 patent applications.

9 Third, we believe the FDA-required  
10 processes or protocols should not be eligible for  
11 patents. Currently drug companies are able to  
12 patent protocols such as the risk evaluation and  
13 medication strategy or REM, a drug safety program  
14 that the FDA requires for certain medications.  
15 Drug companies' ability to patent the mandatory  
16 REMs protocols enables them to use that patent to  
17 block competitors.

18 Granting this type of patent does not  
19 advance innovation. REM's programs are not  
20 inventive and they're easy to replicate. For this  
21 reason we urge the USPTO to cease issuing these  
22 types of patents. We also urge the FDA to de-



1 list this type of patent in the Orange Book so  
2 they cannot be used to delay competitors.

3 On behalf of our community of patients,  
4 thank you for inviting input on your joint  
5 efforts. Nobody benefits more from true clinical  
6 innovation than the patients in our community who  
7 depend on prescription drugs to live and thrive.

8 Again, opponents of reform to your  
9 agencies will argue today, and have already  
10 argued, that the status quo is acceptable. This  
11 collaboration was born out of an acknowledgment by  
12 both of your agencies and this administration that  
13 the correct balance between innovation and  
14 competition is not being struck currently, and  
15 often it results in harm to patients. Increase in  
16 ongoing collaboration between your agencies will  
17 help ensure we strike the better balance that can  
18 result in improved public health through increased  
19 competition and lower drug prices.

20 Thank you.

21 DIRECTOR VIDAL: Thank you, Mrs.  
22 Bourland. Do we have questions from our panel?

1       No questions? All right. Thank you very much.

2               Our next speaker is Mr. Corey Salsberg  
3       from Novartis.

4               MR. SALSBERG: Hi, guys, good afternoon.  
5       On behalf of Novartis thank you very much for the  
6       opportunity to participate in today's listening  
7       session.

8               We are a science-based healthcare  
9       company whose purpose is to reimagine medicine to  
10      improve and extend peoples' lives. I invite you  
11      to learn more about our company in the background  
12      section of my written statement.

13              Let me start by saying that we strongly  
14      share your agencies' goal of ensuring that our  
15      innovation system strikes the appropriate balance  
16      between encouraging meaningful innovation while  
17      supporting a competitive marketplace that can  
18      promote greater access to medicines for American  
19      families.

20              We are concerned however, that the  
21      pursuit of this goal has been unduly influenced by  
22      misleading statements, inaccurate data, and false

1 narratives about the patent system, and our  
2 industry's alleged misuse of it that has dominated  
3 media headlines and permeated political debates  
4 over the last few years.

5 To help keep your work on this goal on  
6 mission we'd like to suggest two things. First,  
7 your agencies should ensure that you carefully  
8 distinguish between actual misuses of the patent  
9 system and legitimate uses that critics simply  
10 call misuse because they don't understand or don't  
11 like how the system works.

12 Second, efforts should be made to ensure  
13 that any data and evidence considered or  
14 incorporated into your work are accurate,  
15 reliable, and relevant.

16 On the first objective, far too often  
17 critics allege misuse simply by employing  
18 inflammatory terms like ever-greening and  
19 thicketing that have no accepted meaning. We  
20 implore your agencies to reject these unhelpful  
21 labels and to instead adopt the thoughtful mandate  
22 that is set forth in the executive order that

1       initiated this dialogue. That mandate asks your  
2       agencies to work together to ensure that the  
3       patent system, while incentivizing innovation,  
4       does not also unjustifiably delay generic drug and  
5       biosimilar competition beyond that reasonably  
6       contemplated by applicable law.

7               This mandating encompasses two very  
8       important principles. One, there's nothing  
9       remarkable or wrong about seeking, obtaining, or  
10      enforcing patents on pharmaceutical inventions in  
11      ways that comply with our nation's patent law.  
12      And two, there's nothing remarkable or wrong about  
13      the appropriate use of those patents to protect  
14      the innovations they cover, which may postpone  
15      entry of generic and biosimilars during the patent  
16      term. The patent system, of course, was designed  
17      to allow just that, which is what creates the  
18      economic incentive and makes it work. It's only  
19      when delays are unjustified that they should raise  
20      any potential concerns.

21              Now these principles provide important  
22      context for this discussion because in the vast

1 majority of cases activities are vilified as  
2 ever-greening and thicketing are not only lawful  
3 but they're critical innovation, and they're  
4 exactly the types of uses that the patent system  
5 was designed to, and should, incentivize.

6 For instance the claim that it is misuse  
7 to obtain multiple patents per product  
8 misunderstands both patent law and the innovation  
9 process. Patents are not issued for commercial  
10 products, they're issued for inventions, which the  
11 law has defined since 1793 to include among other  
12 things, machines, manufactures, processes,  
13 compositions of matter, and any improvements to  
14 any of those.

15 In today's advanced society commercial  
16 products in almost every single field are  
17 comprised of many different patented inventions.  
18 A Smartphone may have as many as 250,000 patented  
19 components, and as you've already heard, a golf  
20 ball may contain as many as 70. With an average  
21 10 to 15 year timeline to develop a single  
22 medicine and an almost 88 percent failure rate, it

1       should not come as a surprise that a technology as  
2       complex as a medicine also typically features many  
3       different inventions by the time of launch.

4               Those inventions, which may include  
5       novel formulations, indications, routes of  
6       administration, and manufacturing methods are a  
7       direct result of our innovation process and they  
8       reflect the many challenges we have to overcome  
9       and the problems that we have to solve to develop  
10      a compound into a single safe and effective  
11      medicine.

12             And because compound patents are  
13      typically filed a decade or more before we reach  
14      that point and only last for 20 years, patents on  
15      further innovations play an important practical  
16      role in helping us realize enough effective patent  
17      term to sustainably finance our work.

18             The related claim that non-compound  
19      patents are undeserving of patents is also wrong.  
20      Sorry, non-compound inventions. The very first  
21      patent issued in America was not for a device or  
22      for a novel ingredient, but for a method of

1 manufacturing potash. In our field, consider the  
2 impact of PCR on DNA sequencing and the lives  
3 saved by Prontosil, the first synthetic antibiotic  
4 that won the 1939 Nobel Prize for medicine. Both  
5 the subject of process or formulation patents, not  
6 compounds.

7 Patents beyond compounds are also at the  
8 heart of the emerging technologies that are  
9 defining our future, such as personalized cell and  
10 gene therapies, gene editing, and RNA based  
11 medicine. Patenting these inventions is not  
12 thicketing, it's an appropriate use of the systems  
13 that reflects the realities of pharmaceutical  
14 science and enables the development of treatments  
15 and cures.

16 As to the frequent claim that  
17 post-launch inventions are undeserving of patent  
18 protection, our patent laws have specifically  
19 incentivized improvements since 1790 precisely  
20 because our founders understood that all  
21 scientific progress builds on what comes before  
22 and that innovation is a process that does not end

1 with the first-generation product. After we  
2 launch a new medicine we continue to look for ways  
3 to make it safer, more effective, useful for a  
4 different disease, or otherwise more beneficial  
5 for patients.

6           Some of our own examples include  
7 converting our Alzheimer's medicine Exelon from  
8 oral form into a transdermal patch to improve  
9 patient compliance and eliminate a gastric side  
10 effect. Inventing our now standard of care heart  
11 failure drug, Entresto, through an innovative  
12 combination of one previously approved and one  
13 never-before approved ingredient, and further  
14 developing our breast cancer drug, Piqray, into a  
15 new drug, Vioice, the first treatment ever to  
16 address the root cause of rare disease PROS.

17           Examples like these which require  
18 substantial additional investment in R&D after the  
19 original medicine was launched are not  
20 ever-greening, they're legitimate uses of the  
21 system to advance and enable further innovation  
22 that benefits patients.



1                   Let me end by briefly addressing the  
2                   issue of inaccurate data. As you've heard from  
3                   others today, study after study has concluded that  
4                   the actual time that new medicines spend on market  
5                   before facing generic competition averages between  
6                   12.2 and 14.6 years, not decades as commonly  
7                   alleged. This is well below the standard 20-year  
8                   patent term that you're supposed to get, and right  
9                   in line with a minimum 14 years that our patent  
10                  term extension systems aims to provide to  
11                  medicines.

12                 Despite this, commonly cited sources  
13                 continue to publish inaccurate data or  
14                 misleadingly add up consecutive terms on separate  
15                 patents without regard for whether those patents  
16                 have any real-world impact on generic entry.  
17                 Because many have written and already spoken about  
18                 these concerns I'll just end with a very quick  
19                 example. A 2017 report from I-MAK claims that our  
20                 cancer drug, Gleevec, had a patent duration of 35  
21                 years and would only face generic competition in  
22                 2029. When in fact generics launched in 2016,

1 almost two years before I-MAK even published its  
2 report. The actual time Gleevec spent on the U.S.  
3 Market without generic competition was less than  
4 15 years. The same report claims that Gleevec was  
5 covered by a total of 73 patents, when the real  
6 number was five, with another one to four possibly  
7 covering the way we make it if you actually opt to  
8 use that particular manufacturing method.

9 So examples like this show why, in our  
10 view, it is imperative that your agencies work to  
11 ensure that you proceed on an accurate, reliable,  
12 and relevant evidence base.

13 Thanks again for the opportunity, and I  
14 look forward to your questions.

15 JUDGE HORNER: Thank you, Mr. Salsberg.  
16 Do we have questions from the panelists? Mustafa.

17 MR. UNLU: Hi. Yes, so you've said that  
18 patent thickets, ever-greening, product hopping,  
19 are terms that don't have any accepted meaning.  
20 Do they have any meaning at all according to you,  
21 or are they part of the inaccurate data that you  
22 were talking about?

1                   MR. SALSBERG: Well the way that they  
2           are most frequently used is to look at the numbers  
3           of patents on a drug and conclude that that's a  
4           patent thicket. What we would say is the question  
5           of whether something is a thicket is whether or  
6           not it's preventing generics from getting on the  
7           market. And as the data systemically time and  
8           again shows, looking at every single FDA approved  
9           drug, you can count on one hand the number of  
10          drugs that gets more than 20 years of effective  
11          patent terms. The average is below what the  
12          system is supposed to give. So that is our  
13          response to thickets.

14                   On ever-greening, again, I mean, you  
15          know, this term is used often interchangeably with  
16          the idea of follow on innovation. And the most  
17          that is written about ever-greening looks at  
18          whether or not a patent was filed after a drug was  
19          first launched in the market and says that  
20          anything beyond that is ever-greening. And this  
21          is the way that these terms are often used.

22                   Number one, there is no accepted

1 definition or consensus on it. And number two,  
2 again, what ought to be looked at from a policy  
3 perspective is how much effective patent term are  
4 innovative drugs getting on the market and when  
5 are generics actually entering. That to us is the  
6 key question.

7 MR. UNLU: Thanks. And that segues into  
8 my second question. You said it's only a problem  
9 when generic competition is unduly delayed.

10 MR. SALSBERG: Uh-huh.

11 MR. UNLU: How would we figure out if  
12 generics are being unduly delayed?

13 MR. SALSBERG: Well I mean I think I'll  
14 start by saying that's of course up to you to  
15 decide what you think is undue. But, you know,  
16 legally speaking I go again primarily back to  
17 patent term. Our patent system globally and in  
18 the United States, is supposed to give 20 years,  
19 and that of course is a generic term that applies  
20 to all fields of technology. In our field it  
21 takes us 10 to 15 years on average before we can  
22 even get our product on the market. So when you

1 look at how much term is right you ought to be  
2 looking at the time from when the product is able  
3 to be launched. Because, rightly of course, the  
4 FDA requires us to do safety and efficacy studies  
5 before we can get there.

6 I would also note that the term even  
7 going back to 1790, the original patent term in  
8 this country was 14 years, which is about what we  
9 get now. Today it's 20, we're not getting that in  
10 almost any case. Sure, there are a handful of  
11 examples of drugs that have gotten more than 20,  
12 but they're very, very rare. So I would say that,  
13 you know, if delays are occurring well below the  
14 20 years that's supposed to happen, that is one  
15 factor to consider. The second factor of course  
16 is to see whether what is being done is compliant  
17 with law. You know, the fact that a patent, a  
18 valid patent that has been granted by the patent  
19 office and has a presumption of validity and has  
20 not been invalidated, is stopping a generic from  
21 infringing that patent and copying the same thing  
22 doesn't mean that that's an undue delay. That's a

1     legitimate delay. That is the whole purpose of the  
2     patent system. And the reason why it's the  
3     purpose of the patent system is because we need to  
4     be able to have that time on the market without  
5     competition in order to fund the average, well  
6     over a billion dollars all the way up to two and a  
7     half, depending on which study you look at, that  
8     it costs to invent each drug.

9             MR. UNLU: Thank you.

10            MR. RITTERBECK: You mentioned a couple  
11     of times that in your view there's a lot of  
12     inaccurate data being presented out there. And I  
13     think the one example you gave was there was a  
14     report that said a drug was covered by a total of  
15     73 patents when in reality it was either somewhere  
16     five to nine.

17            MR. SALSBERG: Yep.

18            MR. RITTERBECK: Do you have any  
19     thoughts on like why or how those discrepancies  
20     are so large and it's not even close?

21            MR. SALSBERG: It's our actual drug so  
22     we can speak directly to it. So that particular

1 case in this I-MAK report. Among the 73 patents,  
2 total patents that were listed, 44 of them were  
3 abandoned patent applications. So not only did  
4 these never issue as patents but of course provide  
5 no exclusivity, but in many cases any subject  
6 matter that is the subject of those abandoned  
7 patent applications would be dedicated to the  
8 public when it's not claimed. So in a way it's  
9 the anti-patent, it's the opposite of a patent,  
10 abandoned patent applications. As for the rest,  
11 one of them was a pending application that I  
12 believe never granted.

13           The rest we don't really know because  
14 I-MAK did not at that time disclose what patents  
15 they were counting. But our best guess is that  
16 these are patents filed by third parties, possibly  
17 some patents that might read on some other version  
18 or aspect of the drug that's not part of the  
19 product. Not the drug, of the ingredient. Maybe  
20 a use that's never been tested. It's not part of  
21 our product so if a generic copies us they are not  
22 going to run anywhere near those patents.

1                   But I think the key figure here is that  
2     44 out of 73, they called them patents and I'll  
3     just remark, you know, unfortunately, this figure  
4     was picked up in the Staff Majority House  
5     Oversight Report that was just previously  
6     referenced by the previous speaker, as a fact. 73  
7     patents is the fact that's quoted, and you can see  
8     that unfortunately this data that originates in  
9     unchecked third-party sources is now being picked  
10    up by official sources as well without any further  
11    checking as to its accuracy.

12                  And that's why, you know, we share  
13    Senator Tillis' concern in the letter he wrote to  
14    your agencies last year that before you start  
15    relying on this data it's very important that you  
16    look at its accuracy. And if it's accurate, then  
17    by all means you should use it, but let's make  
18    sure that we're actually checking the legitimacy,  
19    the reliability, and the reasoning and the logic  
20    before we start citing it in official reports.

21                  JUDGE HORNER: All right. No further  
22    questions. Thank you, Mr. Salsberg. And our



1 final speaker for Session 4, Mrs. Azeen James of  
2 Fresenius Kabi.

3 MRS. JAMES: Hello, my name is Azeen  
4 James, I'm Vice President and Chief ID Counsel for  
5 biosimilars at Fresenius Kabi. Fresenius Kabi is  
6 a healthcare company specializing in bringing low  
7 cost medicine to patients, including sterile  
8 injectable generics and biosimilars. Thank you  
9 for including me in the listening session today.

10 At the outset I just wanted to second  
11 the comments that were made by Professor Tu  
12 regarding the misuse of obviousness type double  
13 patenting in terminal disclaimers. As Professor  
14 Tu highlighted, there is peer review data that  
15 clearly shows that patent thickets are delaying  
16 market entry for generics and biosimilars.

17 And the fact that these terminally  
18 disclaimed patents expire on the same date doesn't  
19 solve the problem. Basically it's a numbers game.  
20 And as Ms. Bourland noted, it's the mass number of  
21 patents that is a barrier for market entry.  
22 Biosimilars especially do not enter the market

1       when you have this large number of patents.

2               Now turning to the topic of the  
3       USPTO/FDA coordination, I'm going to focus on a  
4       specific tactic that's commonly being used by  
5       branded drug companies, and I think this is an  
6       actual example of a misuse that you can see  
7       happening in the patent system.

8               So the practice involves two steps. The  
9       first one is the branded drug company files a  
10      patent to cover the backbone of the drug, the  
11      structure of it, the amino acid sequence, peptide  
12      sequence. And that's what we primarily call the  
13      product patents.

14              But then an ancillary patent is filed  
15      years later that is directed to claiming technical  
16      features of that molecule. This is not something  
17      that's an improvement, it's not innovative, it's  
18      actually technical features that are present on  
19      the drug that was patented earlier. And examples  
20      of these technical features are glycan profiles,  
21      charge profiles, variants, impurity levels,  
22      etcetera.

1                   Now the difference between the filing  
2     dates of the principle product patent and the  
3     ancillary product patent and the subsequent expiry  
4     dates basically allows a patent owner to put an  
5     early stick in the sand covering the product, and  
6     then improperly prolonging that monopoly on the  
7     actual product patent beyond the expiry of the  
8     primary product patent.

9                   Now when pursuing this strategy it's  
10    necessarily a branded drug company withholds  
11    information from the USPTO. This is not the same  
12    thing as providing inconsistent statements to the  
13    FDA and PTO because to get the approval they  
14    actually have to provide these technical details  
15    to the FDA. This is more of a selective  
16    information sharing. And it's, you know, the  
17    case, the Hospira case that Mr. Korn mentioned  
18    doesn't really apply here because we're not  
19    talking about inequitable conduct or  
20    misrepresentation, this is what they select to  
21    disclose to the FDA.

22                  And unfortunately because what they've

1 disclosed to the FDA is confidential, a patent  
2 examiner who is examining the ancillary product  
3 patent doesn't have access to that information to  
4 determine whether it's prior art or not to this  
5 kind of ancillary product patent with these  
6 technical features.

7           And this is a tactic that as a  
8 biosimilar company we're seeing more and more  
9 often used by branded drug companies. In our  
10 written submissions we gave several examples of  
11 molecules where we have seen that, but just to  
12 highlight a couple. For example the product  
13 Herceptin, which is trastuzumab. The actual  
14 peptide sequence was covered by an application  
15 filed in 1991, but then in 1999 in a separate  
16 application, claims were filed to cover the acidic  
17 profile of the same molecule.

18           For Actemra, Tocilizumab, the claims of  
19 the peptide were covered in an application filed  
20 in 1992, and almost two decades later a new  
21 application was filed in which they claimed the  
22 glycosylation profile. So basically these aren't

1 improvement patents, these are product patents  
2 that are just going after a specific technical  
3 feature on the molecule.

4 Now we believe that there are two simple  
5 ways that the agencies can address this  
6 gamesmanship and to stop it. One, we think that  
7 the USPTO could encourage patent examiners to  
8 source prior art material regarding that primary  
9 principle product patent. That way the examiners  
10 have access to information to determine whether  
11 the primary product patent is relevant prior art  
12 to the ancillary technical feature patent.

13 These sources could be lists of  
14 applicants, published patent term extension  
15 response for the drug, drug bank databases,  
16 commercial databases that talk about product  
17 approvals, and especially FDA guidance documents  
18 that show whether for regulatory approval such  
19 technical data was required to be disclosed.  
20 Because that will show that the branded company  
21 had that information and that is nothing novel or  
22 new or improved.

1           Second, examiners should be able to talk  
2     to someone at the FDA with questions regarding the  
3     technical features that the second patent is being  
4     sought. This information can help the examiners  
5     determine whether that primary patent is prior art  
6     and whether the ancillary claims are either  
7     anticipated and/or obvious over the first one.  
8     The FDA could answer questions regarding the  
9     specific technical information, they could provide  
10    documents showing the guidance which could serve  
11    as prior art against the ancillary patents, and  
12    they could provide relevant extracts related to  
13    that specific technical feature that's being  
14    sought.

15           Now as we all know, FDA dossiers are  
16    hundreds of thousands of pages long, but to ease  
17    the burden on examiners we could have the selected  
18    few pages that relate to that specific technical  
19    feature be provided to them.

20           And to ease the burden on the FDA, we  
21    think that this kind of collaboration could be  
22    limited to approved products. And that way you

1       limit, substantially reduce the number of patents  
2       that are at issue and the number of patents for  
3       which an examiner may need support on.

4               Finally, we think the onus shouldn't  
5       just be on the agencies, we think that patent  
6       applicants should provide statements to the USPTO  
7       that the information they provided them is  
8       consistent and the same that they've provided to  
9       the FDA. And that kind of puts more of  
10      inequitable conduct pressure on them as well to  
11      ensure that the examiners have the right  
12      information for the analysis.

13              Again, thank you very much for inviting  
14      me to this, and I'm happy to answer any questions.

15              JUDGE HORNER: Thank you, Mrs. James,  
16      for your comments. Do we have any questions from  
17      the panel? Mustafa.

18              MR. UNLU: Yeah. So, thank you, that's  
19      fascinating information. So if I understand  
20      correctly, the first patent is filed for an amino  
21      acid sequence and then there are some years that  
22      pass and then there's a patent for glycosylation

1 patents?

2 MRS. JAMES: Right.

3 MR. UNLU: Does it take that long to get  
4 that information, or is that obtained normally  
5 when you first create the molecule? I'm trying to  
6 understand what part of improvement --

7 MRS. JAMES: That information is  
8 available when that first product patent is  
9 disclosed. So our position is that the patent  
10 applicant should apply for the claims for those  
11 technical features at that same time too. But by  
12 them withholding that glycosylation information  
13 and filing it a decade later, it actually prolongs  
14 the product patent by another decade. So it's  
15 information that's inherently in the molecule and  
16 is disclosed to the FDA in order for the drug to  
17 get approval.

18 MR. UNLU: Yeah, so this is going to  
19 demonstrate my ignorance of patent law. But how  
20 is that patentable if it's already known?

21 MRS. JAMES: Because the examiner  
22 doesn't know that it is known. So the examiner



1 gets this application and basically talks about  
2 let's say Manos 5 glycan at a certain percentage  
3 on a certain amino acid. And the patentee says  
4 that this is, you know, newly discovered  
5 information that helps the activity of this drug.  
6 However, that information was available a decade  
7 before when the actual amino acid sequence was  
8 filed. Because in order to meet the activity,  
9 that amino acid sequence inherently had that Manos  
10 5 glycan profile.

11 MR. UNLU: And that information is  
12 provided to FDA as well. And your suggestion is  
13 they should be shared -- you also heard concerns  
14 about confidential information being shared  
15 because as you know, information in FDA is  
16 confidential and we can't disclose it, and  
17 apparently it's not as it comes to the PTO.

18 MRS. JAMES: Yes, and that's a very  
19 valid concern. I know that there is statutes, you  
20 know, that allows the USPTO to keep it  
21 confidential. But I do know that one of the  
22 speakers this morning mentioned a valuable thing

1       in that some other people need to have access to  
2       that information to be able to know why the patent  
3       was invalid.

4               So I do think there needs to be more  
5       thought put into how that information is kept  
6       confidential with the PTO, but it's definitely  
7       prior art that's out there that a biosimilar  
8       company or the patent examiner doesn't have access  
9       to. And it's a gamesmanship that's being played  
10      often with biosimilars products, with biologic  
11      products.

12             MR. UNLU: Okay. Thank you.

13             MRS. JAMES: Thank you.

14             MS. EVANS: Thank you for your comments.  
15      You mentioned that because the patent applications  
16      or patents expire on the same date does not help  
17      the problem, it's the number of patents that stops  
18      the biosimilars. Can you speak a little more to  
19      that, please?

20             MRS. JAMES: Sure. So as a biosimilar  
21      manufacturer, when you start to pick the products  
22      that you're going to develop one of the first

1 things you do is you do a patent landscape, right?  
2 Because you want to make sure that you don't  
3 infringe any patents and you want to abide by the  
4 law.

5 So when you come across a biologic that  
6 let's say has 100 patents surrounding it, my job  
7 is to go to my senior management and say, look,  
8 here are these 100 patents. In order for us to  
9 get on the market on X date we have to either  
10 design around certain patents or we have to  
11 invalidate all these patents.

12 So then it becomes a numbers game  
13 because in order to file IPRs we have to file IPRs  
14 against every patent and every claim. And that's  
15 about a million dollars per patent. So if I have  
16 to challenge 50 patents that's \$50 million I don't  
17 have. And as you know, there's certain arguments  
18 that we can't even use in an IPR. And then  
19 there's the issue of standing of whether we can  
20 appeal it or not.

21 So then when my senior management looks  
22 at that number of patents, even if the expiry

1       date's the same, they say, you know what, let's  
2       put this biologic to the back of the line and  
3       we'll develop it later.

4               And so instead of us coming on the  
5       market, let's say in 2024, we may not come on the  
6       market until 2029 because we're not going to  
7       invest the resources to develop this if we have to  
8       spend hundreds of millions of dollars fighting  
9       these patents.

10              So that's where the number thing  
11       discourages you to come to market. Because  
12       biosimilars won't even put it in the line of  
13       developing. And the earlier we can develop the  
14       earlier patients can have access to a lower cost  
15       medicine.

16              JUDGE HORNER: Go ahead, Dan.

17              MR. RITTERBECK: Thanks for your  
18       comments. Just a quick I guess comment or  
19       question. In your comments you mention that  
20       there's peer reviewed data that shows that patent  
21       thickets are delaying generic and in biosimilar  
22       competition, and forgive me if I missed it, but I

1       didn't see a citation to that peer review data, so

2       --

3               MRS. JAMES: I actually believe in our  
4       written submissions there's a footnote, I hope I  
5       put it in there. There's a recent paper that was  
6       just published by Denver University Law Professor  
7       Dr. Chao, and Rachel Goode, that looks at  
8       biosimilars on the market and looks at the number  
9       of patents and the timing of when they came on the  
10      market, I think that analyzes it. And I believe  
11      that Professor Tu also has some papers that  
12      address those issues.

13             MR. RITTERBECK: Perfect. Thank you.

14             JUDGE HORNER: I think we have one more  
15      question.

16             MS. FERRITER: Thank you very much. And  
17      I apologize for just asking you this question but  
18      I'm about to leave here, and a number of others  
19      have made the same point about the situation where  
20      there's obviousness type double patenting and  
21      statements where there's a terminal disclaimer if  
22      the first patent is invalidated, everything else

1       should. As you know, a patent would have multiple  
2       claims of the obviousness type double patenting  
3       rejection. Usually it's over just one or more  
4       claims but not all of the claims in the patent.  
5       Can you help me understand why the whole network  
6       of patents should stand or fall even though the  
7       claims could be quite different?

8               MRS. JAMES: So, you know, when a patent  
9       continuation is granted over an obviousness type  
10      double patenting rejections, terminal disclaimers  
11      filed, the whole patent gets the terminal  
12      disclaimer over the patent.

13             And as a biosimilar, we basically, let's  
14      say there's five patents in the first one and  
15      there's 10 patents in the second one, we have to  
16      invalidate every relevant patent that goes under  
17      there. And so again, it becomes a numbers game  
18      for us because the more, you know, so for a  
19      branded company it's an actual economic benefit.  
20      You just give them money and you get multiple  
21      patents and then we have to bring it down. They  
22      are basically the same, the reason they got the

1 non-obviousness double patenting rejection was  
2 because they were claiming the same specific  
3 thing.

4 So it is really a patent claim-by-claim  
5 analysis but I think that's how the terminal  
6 disclaimer function works within the patent  
7 system.

8 JUDGE HORNER: Yes, I think Karin's  
9 point was that if there's one claim in a patent  
10 that's deemed to be an obvious variation of  
11 another claim in a different patent, but there are  
12 19 other claims in that patent that are not  
13 obvious, they did not get the double patenting  
14 rejection. And if we tie all of those patents  
15 together then claims may fall that wouldn't have  
16 otherwise been subject to that rejection.

17 MRS. JAMES: Yes, and as a biosimilar  
18 really our concern is that claim in which we  
19 either are being asserted that we infringe or  
20 we're invalidating. So I understand what you're  
21 saying. And I think, you know, that's just like a  
22 claim-by-claim kind of --

1 JUDGE HORNER: I'll just take this  
2 opportunity to highlight for those listening and  
3 here today that our technology center that  
4 examines pharmaceutical applications has been  
5 doing recent training for examiners, both  
6 refresher training and enhanced training on  
7 obviousness type double patenting so that they're  
8 able to identify those instances where that is  
9 happening and can certainly raise rejections when  
10 they're proper to be raised.

11 We're going to take a break. I know  
12 we're running a little bit long so it's 3:28.  
13 We'll come back and start the next session at  
14 3:38. So we'll take about a 10 minute break.

15 (Recess)

16 JUDGE HORNER: We're going to go ahead  
17 and get started. So if everyone can take their  
18 seats. This microphone is --

19 JUDGE HORNER: Yes. Okay. Thank you.  
20 We are ready for our last session of the day. And  
21 before we get started, I'll go ahead and ask our  
22 panel members to introduce themselves one more



1 time.

2 MR. UNLU: Good afternoon. I'm Mustafa  
3 Unlu. I'm at the Office of Therapeutic Biologics  
4 and Biosimilars at the Center for Drug Evaluation  
5 and Research in the Food and Drug Administration.

6 MS. DAVIS: Hi, I'm Kristin Davis.  
7 Director of the Office of Generic Drug Policy in  
8 the Office of Generic Drugs at CDER at FDA.

9 MR. RITTERBECK: Good afternoon,  
10 everyone. My name is Dan Ritterbeck. I'm a  
11 regulatory counsel in CDER's Office of Regulatory  
12 Policy at FDA.

13 MS. TERROT: I'm Marianne Terrot. I'm  
14 an Associate Chief Counsel in the FDA's Office of  
15 the Chief Counsel.

16 JUDGE HORNER: I'm Linda Horner,  
17 administrative patent judge on the Patent Trial  
18 and Appeal Board for the USPTO.

19 MS. TILL: Mary Till in the Office of  
20 Patent Legal Administration at the USPTO.

21 MR. SALIMI: Hi. Ali Salimi, from  
22 Office of Legal Administration. I work with Mary

1 Till.

2 JUDGE HORNER: Okay. Thank you. So,  
3 our session five the primary topic is patent term  
4 extension and patent use codes. And our first  
5 speaker is Mr. Victor Van de Wiele? Van de Wiele  
6 from Harvard Medical School.

7 MR. VAN DE WIELE: Thank you very much.  
8 So, I'm representing today the program and  
9 regulation of therapeutics in law at Harvard  
10 Medical School, and especially our work on patent  
11 term extensions from the past and present as well.  
12 Essentially what I'll be saying is quite short,  
13 but what we did is we replicated the methodology  
14 of one of our existing papers back in 2017, and we  
15 looked at all the drug approvals between 2018,  
16 that is type one and type two drug approvals. So,  
17 the new molecular entity and the new active  
18 ingredient, and we paired that with the USPTO's  
19 website on patent term extensions from looking at  
20 potential correlations between these data.

21 We made a couple of interesting  
22 findings, and I think presenting these here today

1 might incite debate on the current status quo  
2 based off of the data. So first of all, we found  
3 that half of all drugs examined were associated  
4 with PTE. So that means out of 600 plus drugs,  
5 there's a grand total, 319 patents received or  
6 related or received patent term extension. Now  
7 the median exclusivity, so that is the point of  
8 drug approval of a drug until, and this is  
9 something we came up with, until the expiry date  
10 of the patent that received the patent term  
11 extension was 12.92 years. So that is for both  
12 small molecules and biologic drugs. This is the  
13 median of that cohort. The patents that we looked  
14 at were generally, not generally, one third of  
15 those patents were secondary patents. That means  
16 that contrary to mainstream beliefs not all  
17 patents that receive PTE are primary patents.  
18 There was also one third that were secondary  
19 patents.

20 Third, 20 per cent of those patents, so  
21 there's 319 patents, were BLA related. So those  
22 were related to a biologic drug. Why is that

1 important? Because we know that biologics already  
2 received 12 years of regulatory exclusivity. And  
3 what we found is that on average, the market  
4 exclusivity this term, again for biologics was  
5 13.5 years. So that means beyond those 12 years  
6 regulatory exclusivity already, biologics received  
7 1.5 years extra to enforce a patent that received,  
8 sort of, key patent in court to extend their  
9 market exclusivity beyond that regulatory  
10 exclusivity. Then we also found finally that 45  
11 percent of these patents were litigated, but only  
12 a fraction ended up being invalidated. So that  
13 means that these are generally strong patents,  
14 which makes sense because two thirds of these  
15 patents that we looked at were primary patents  
16 which were associated with the active ingredient,  
17 but then also means that the other half wasn't  
18 litigated at all or wasn't tried to be enforced or  
19 maybe it was, but it didn't. Or maybe  
20 manufacturers looked at it and said, actually,  
21 there's no way we'll be able to invalidate this.

22 So, what are what are these findings



1 grants or little even pursuit of applications for  
2 these drugs indicate that we should rethink the  
3 relevance of patent term extensions in the 21st  
4 century. They were relevant in 1984 when the  
5 Hatch-Waxman Act was enacted. But maybe now, with  
6 the advent of patent thickets, maybe enforcing  
7 your key patent is no longer the way to get as  
8 much exclusivity out of your out of your  
9 innovative product as possible. And therefore, I  
10 think it's important that this discussion is being  
11 held and that the USPTO and FDA think about ways  
12 in which patent term extensions are still relevant  
13 and whether there should be caps on whether they  
14 are granted or not. So, thank you for the  
15 opportunity.

16 JUDGE HORNER: Thank you for your  
17 comments and for sharing with us your research.  
18 Do we have any questions from the panel?

19 MR. SALIMI: I have a quick question.  
20 In reading the materials submitted, maybe I  
21 misunderstood, but you said only 48 per cent of  
22 the BLAs get ask for patent term extension. Is

1       that true?

2                   MR. VAN DE WIELE:  No.  So, we only  
3       looked at the amount of BLAs that actually -- so  
4       the BLA is with patent term extension and within  
5       that cohort.  So, 75 percent were associated with  
6       secondary patents.  That's the main finding for  
7       BLA, for BLAs.  Yeah.

8                   MR. SALIMI:  I see.  In examining or  
9       reviewing our process for patent term extension,  
10      did you come across anything that we have done  
11      wrong in processing these applications?  Have we  
12      neglected any statutory consideration for patent  
13      term extension?  Have we given extra patent term  
14      for any wasn't warranted.

15                  MR. VAN DE WIELE:  No.  I think the  
16      process is working just as it was intended to  
17      work.  The only thing that we have to rethink  
18      whether larger molecules, the BPCIA introduced  
19      biosimilars and covered biologics, but it was a  
20      different act.  In the Hatch-Waxman Act, there  
21      were different compromises that were made.  And I  
22      just think generally what we focused on is that

1       these biologic drugs are applying for it, but  
2       maybe they shouldn't be receiving it in the first  
3       place. But I think the system works exactly as  
4       it's done, and the terminal disclaimer is always  
5       present, and I think the USPTO did well in that  
6       sense. Yeah.

7               MS. TILL: Yeah, I just had one question  
8       that you were talking about, the data exclusivity  
9       that protects something different than what  
10      patents protect. So, you're I think -- is your  
11      opinion that because 12 years of data exclusivity  
12      is granted for biologics, that they don't need to  
13      have the extension under 156, even though it's a  
14      different type of protection?

15             MR. VAN DE WIELE: Well, you have to  
16      think, right, is that regulatory exclusivity  
17      really still relevant if, you know, for most  
18      biologics or biosimilars that try to enter the  
19      market litigation precedes it. And the litigation  
20      is actually the way to measure how long or when  
21      biosimilars can enter. So, I think the patent  
22      term extension aids the problem of patent thickets



1 or whatever you want to call them and by extending  
2 the time during which litigation needs to take  
3 place. And that litigation is exactly what causes  
4 the delays in biosimilar entry.

5 MR. UNLU: Hi. Thank you for your  
6 presentation. I have a quick -- couple questions.  
7 When you said mean exclusivity, this is from  
8 approval to the date of entry of follow on  
9 product, and it includes a patent term extension.  
10 So everything you looked at had a patent term  
11 extension or not everything?

12 MR. VAN DE WIELE: No. So, the median  
13 exclusivity is from a drug approval date to the  
14 expiry date of that extended patent. So that  
15 doesn't mean that by the time that first that  
16 patent expires, biosimilars enter, it's just the  
17 measure, that this is how much time we truly think  
18 the mean -- that if there is one patent that will  
19 be litigated that's that extended patent and  
20 that's kind of truly the market exclusivity of a  
21 drug, not just the regulatory exclusivity, because  
22 the fact that main patent is present means that it

1 is still up for litigation, that it's a strong  
2 patent because that is a conception that patents  
3 within the patent term extension are strong  
4 patents and are difficult to litigate. Yeah.

5 MR. UNLU: So, you didn't look at actual  
6 entry date you just looked at how long that was  
7 left on the patent after extension.

8 MR. VAN DE WIELE: That's correct. Yeah.

9 MR. UNLU: And what -- is there a  
10 standard deviation on these numbers?

11 MR. VAN DE WIELE: Yes. Did I not  
12 provide them in my comments?

13 MR. UNLU: I will look.

14 MR. VAN DE WIELE: Okay. Sure. Sorry.

15 MR. UNLU: Thanks.

16 JUDGE HORNER: Any other questions.  
17 Okay. Thank you.

18 MR. VAN DE WIELE: Thank you.

19 JUDGE HORNER: We'll move to our next  
20 speaker, Ms. Emmabella Rudd with T-1  
21 International.

22 MS. RUDD: Good afternoon. My name is

1 Emmabella Rudd. And since the age of five, my  
2 life has depended on insulin. Currently, I reside  
3 in Washington, D.C., where I'm pursuing my Masters  
4 in Health Policy at Georgetown University. For  
5 many years, my work has encompassed advocacy for  
6 insulin prices as well as diabetes research at  
7 both state and federal levels. At the age of  
8 five, I was suddenly struck with symptoms of  
9 Type-1 diabetes, frequent urination, extreme  
10 thirst and significant weight loss with no family  
11 history of the disease. I was almost  
12 misdiagnosed, and if I would have been diagnosed  
13 the next day, I would have lost my life.

14 Now, 16 years later, and my chronic  
15 disease continues to be profited off the system  
16 due to exploitation of the patent system. Today I  
17 am testifying to say that the PTO and FDA should  
18 carefully scrutinize patent applications to ensure  
19 that pharma companies do not receive longer patent  
20 monopolies than they are entitled to under the  
21 law. Drug makers often argue that additional  
22 patent applications filed prior to regulatory

1 approval incentivize companies to invest in the  
2 development of a new drug and should not be  
3 characterized as ever-greening. However, the drug  
4 makers' intentions are not as transparent as they  
5 seem. By doing this, they stifle generic  
6 competition. Are these patents justifiable when  
7 the drug's improvements are not groundbreaking to  
8 those that use it?

9           We as patients want to see novel and  
10 groundbreaking technologies that will improve our  
11 lives as diabetics. Since the age of five, I've  
12 seen incredible breakthroughs. However, we just  
13 continue to see patents on technologies that have  
14 not changed for an extended period of time. Very  
15 excitingly, just in November of 2022, TZIELD was  
16 passed by the FDA. A drug that will delay the  
17 onset of Type-1 diabetes by two years. Currently,  
18 the cost of this treatment is \$193,000 for the 14-  
19 day treatment. If I had the choice to delay the  
20 onset of my diagnosis when I was diagnosed at the  
21 age of five, I would take it without hesitation.

22           But would I be able to afford it? The

1 price tag for TZIELD is out of reach for many, and  
2 if the manufacturer applies for and receives more  
3 patents, whose terms extend after its original  
4 patent expires, which is likely to do, given the  
5 current policy to yield will continue to be  
6 inaccessible for Americans. The high and  
7 inaccessible price of this will ultimately  
8 increase US health care spending and not improve  
9 the reality of Type-1 diabetes patients. Already  
10 we see limited lifespans. We will be at risk for  
11 worse health outcomes, not having the access to  
12 this drug. If the intent of TZIELD's  
13 manufacturers is to work towards a world with  
14 option to delay the onset of type one diabetes,  
15 patent ever-greening should not be an option in  
16 this case. The option to profit more due to  
17 endless market exclusivity should not be an  
18 option. Generics should be launched as quickly as  
19 possible to improve public health in the United  
20 States. I think that TZIELD is a novel and  
21 innovative new medicine right now in a successive  
22 lifetime of a lifetime and an innovation. And I'm

1 extremely excited for that.

2           However, many insulins are not. We  
3 should overall raise the incentive standard  
4 required for patients or for patents. This would  
5 make manufacturing and biosimilars and  
6 interchangeable insulins and other diabetes  
7 technologies and cures a more worthwhile  
8 investment for new manufacturers and competitors.  
9 With this said, PTO should carefully scrutinize  
10 every aspect of pharma companies' extension  
11 applications, including applicants' compliance  
12 with the PTO's duty of disclosure. Lastly, PTO  
13 should invite third party participation in the  
14 extension process, including participation by  
15 patient groups. As patients we're the experts.  
16 We should be included in every step of the way as  
17 we are utilizing these drugs to stay alive. I  
18 can't go without just a couple of hours of  
19 insulin. And neither does any other Type-1  
20 diabetic.

21           We should be included in every step of  
22 the way as we are utilizing them to stay alive.

1       That is, at the end of the day, the most  
2       important. Now, this could look like or operate  
3       as a disease specific patient coalition or working  
4       groups to review patents and/or to provide  
5       training to the PTO and FDA. And what this looks  
6       like in our day to day lives. How do these drugs  
7       impact us and do the new patent applications  
8       really affect us? Patients, like I said, need to  
9       be at the table as our lives are at stake.  
10      Pharmaceutical companies have been invited to the  
11      table for years, yet we as patients have been left  
12      out and are not being recognized as experts we  
13      are. The PTO and FDA at its foundation is  
14      existing to serve the health and wellbeing of the  
15      American people and not to prioritize the market  
16      and its manufacturers for profit. In order for  
17      this system to work, patients need to be included  
18      in the conversation always. Thank you.

19               JUDGE HORNER: Thank you, Ms. Rudd.  
20      Thank you for being here today and for sharing  
21      your perspective as a patient and your advocacy  
22      for the system and for the patient population with

1     Type-1 diabetes. I'm intrigued by what I've heard  
2     today from you and from a few of the other  
3     speakers about getting patients more involved.  
4     Particularly, I know there's some patient advocacy  
5     and patient advisory groups at FDA. We don't  
6     really have anything like that currently at PTO,  
7     but certainly that's something we're going to  
8     explore. So, I appreciate your input and  
9     recommendations here on that point specifically,  
10    and I'll open it up for the other panel members if  
11    anyone has any questions. No other question.  
12    Okay. Thank you very much.

13                 MS. RUDD: Thank you.

14                 MR. SALIMI: I have a question.

15                 JUDGE HORNER: Oh, go ahead.

16                 MR. SALIMI: Yes. Thanks for being  
17    here. You advocate that we should ask from FDA,  
18    to get engaged with the FDA more so. The question  
19    is third parties can petition the FDA to determine  
20    when it comes to their regulatory review period.  
21    But under what statutory authorization do we have  
22    to request for that? Do you have any ideas



1       whether we have the statutory authorization to  
2       request FDA for the PTO redetermination?

3               MS. RUDD: Currently, I don't have the  
4       answer to that, but I can get back to you in the  
5       written comments. But as far as overall, just the  
6       inclusion, I think at this time, you know, it's  
7       like you had said that there are groups, working  
8       groups that stand. I think it's important that we  
9       look into that and try to bring that to the table  
10      for now. But as far as the statutes, I am not  
11      familiar, but I can provide that in the comments.

12             MR. SALIMI: Yeah, but you know, you can  
13      take an active, more active participation when the  
14      FDA publishes these, their regulatory review  
15      period in the Federal Register. And if you guys  
16      and your group have any question regarding the  
17      time, that's when you can act and file a petition,  
18      us in the USPTO, we really don't have any  
19      authorization to question what the FDA gives us.  
20      So that's just something to keep in mind.

21             MS. RUDD: Okay. Thanks.

22             JUDGE HORNER: And I'll also note here

1       that we've recently, the PTO has recently enhanced  
2       the information on our Web page so that when PTE  
3       applications are filed, there's an easy way to  
4       identify those through our Web page so that if  
5       third parties do want to challenge in a petition  
6       to the FDA, they are aware of those PTE  
7       applications when they're filed. So, we're trying  
8       to increase the transparency there on that issue.

9               MS. TILL: I had one question. You were  
10       mentioning this newly approved product called  
11       TZIELD, that is a biologic for delaying the onset  
12       of Type-1 diabetes. I guess the question I have  
13       is, that's a biologic product, so it would be  
14       subject to the data protection exclusivities of  
15       the BPCIA, and that's a 12-year data exclusivity.  
16       Do you, in your opinion, do you believe that  
17       that's something that is then a barrier to  
18       bringing biosimilars, or is that just you  
19       anticipate that at that, the time that that  
20       exclusivity is lapsed, that a biosimilar would  
21       potentially be available?

22               MS. RUDD: Absolutely. So, we've heard

1 from other speakers today talk about how after  
2 these 12, 14-year, you know, patent market  
3 exclusivity, they're limited to just that one and  
4 the price will most likely stay high. But after  
5 that, 14 years, and that's how it's always  
6 operated. And yes, it limits who can access it  
7 because it limits, okay are private insurance  
8 companies going to cover this. Definitely depends  
9 on the patient and what health care they receive.  
10 Right. However, after the 14 years, they could  
11 take advantage of perhaps filing for another  
12 patent and that could limit more access to  
13 patients later.

14           So that could keep the price high, that  
15 could keep market exclusivity very streamlined.  
16 And so, what I am saying here is that I don't want  
17 the drug manufacturers to take advantage of that.  
18 I believe that at this foundation that they want  
19 this to be accessible to patients and to put off  
20 the two-year mark of Type-1, you know, living with  
21 Type-1 diabetes is very difficult. And year after  
22 year if you're, you know, despite how well you

1 take care of yourself, it's going to hurt your  
2 health. And so, if they have that two year, it's  
3 going to make a huge difference. Right.

4 And so, what I -- myself and I can speak  
5 on behalf of other Type-1, we want to see that  
6 accessible and we don't want it to see it being  
7 taken advantage of. We want to see more  
8 innovation. We want to see that two-year become  
9 four years and eventually, hopefully a cure.  
10 However, we want it to see it be accessible. We  
11 don't want patents to be part of that limitation.  
12 So --

13 JUDGE HORNER: Thank you very much.  
14 We'll move to our next speaker, Ms. Patricia  
15 Kelmar from the US Public Interest Research Group.

16 MS. KELMAR: Thank you. Yes, I'm  
17 Patricia Kelmar. Thank you for having me today  
18 and thanks for sticking it out. I know we're  
19 getting to end of a long day, but I'm the Senior  
20 Director for Health Care Campaigns for US PIRG,  
21 which is the Public Interest Research Group. We  
22 are a nonprofit, nonpartisan consumer advocacy

1 organization with grassroots members in our 24  
2 states. Working to address high health care  
3 prices, we support improved access to generic and  
4 biosimilar drugs because we know that a  
5 competitive health care market helps to keep  
6 prices in check.

7           The FDA's own data shows that with even  
8 just one generic alternative, you can bring prices  
9 for that drug down by as much as 40 per cent.  
10 That's a lot of savings. We applaud your agency's  
11 joint commitment to collaborating to improve  
12 access to generic and biosimilar drugs. And thank  
13 you so much for the opportunity to speak today. I  
14 think all of us here is patient and consumer  
15 advocates are seeing this as one of those  
16 opportunities to play a role, an active role  
17 without having to figure out how to formally  
18 submit comments and go through portals and keep  
19 track of regulatory notices and the things that  
20 people with a bigger staff might be able to do.  
21 So we thank you for this more informal but  
22 important opportunity to speak.

1                   Drug prices, as you all know, drive up  
2     the cost of health care for patients, for insured  
3     families, and our state and federal health  
4     programs. Two thirds of US adults rely on  
5     prescription drugs, and yet one in four people  
6     struggle to pay for them. When people can't fit  
7     drugs in their monthly budgets, they make  
8     decisions that negatively impact their health,  
9     such as not filling prescriptions at all or  
10    skipping doses. And those high prices impact  
11    beyond the patient community, all insured people,  
12    because drug expenses make up about 20 per cent of  
13    our insurance premiums. And when drug prices go  
14    up, so do our premiums.

15                  But we can change that by doing more to  
16    allow generic competitors to come to market.  
17    Savings from new generic approvals are dramatic,  
18    as the FDA's own study shows \$10 to \$20 billion  
19    every year over the last couple of years. And  
20    that's the power of a competitive marketplace.  
21    Unfortunately, recent use of misuse of patents by  
22    pharmaceutical companies is undermining the price

1 competition. Patents are meant to spur  
2 innovation, but the monopoly pricing granted by a  
3 patent isn't meant to last forever. These days,  
4 drug makers spend significant time and money  
5 obtaining new patents for medications already on  
6 our pharmacy shelves.

7           They're blocking our access to generics  
8 and biosimilars. And although a wrongly granted  
9 patent or a weak patent can be challenged in  
10 federal courts, these challenges take years and  
11 come with an average median cost of three and a  
12 half million dollars per case. So, it's no wonder  
13 that we don't see, you know, more challenges to  
14 some of the patents that have been granted. We'll  
15 offer just a few of the recommendations to support  
16 access to lower cost generics and biosimilars, and  
17 you'll find more details in the written comments  
18 that you have before me. But in the interest of  
19 time, I'll try to summarize more quickly. Less  
20 emphasis on -- so our first recommendation is less  
21 emphasis on swift review and more emphasis on  
22 quality review.

1                   Part of the PTO's own mission is to  
2     provide high quality and timely examination of  
3     patent applications. With only 8000 patent  
4     examiners reviewing 600,000 patent applications  
5     every year, patent examiners are under great  
6     pressure to work quickly to serve the clients, the  
7     patent applicants. A 2016 PTO presentation shows,  
8     in fact that 55 per cent of a patent examiner's  
9     performance appraisal is based on productivity and  
10    docket management. And the result is that  
11    examiners spend an average of just 19 hours per  
12    application. This emphasis on swift reviews works  
13    against the PTO's mission to also provide high  
14    quality patent examinations. And the tension is  
15    clear. We understand that you may increase, you  
16    may be considering increasing patent examiner  
17    time, and we applaud that change.

18                  It's time to shift away from the  
19    overemphasis on speed and urge a return to your  
20    mission's directive to serve the public, taking  
21    the time to conduct high quality examinations  
22    which could benefit by having less over patenting



1 fewer patent thickets and a rejection of overly  
2 broad patents. Our second recommendation is to  
3 urge more stringent review of patent applications  
4 for prescriptions already on the market. And this  
5 is where you might be wanting to spend some of  
6 that extra time. Patent applicants should clearly  
7 disclose when a new application, including a  
8 continuation application claims aspects of a drug  
9 already on the market.

10 Those applications should be assigned to  
11 more experienced examiners who should get that  
12 additional time. Examiners need access to a wider  
13 array of information for prior art searches,  
14 including the scientific information provided to  
15 the FDA by drug companies. I've understood that  
16 there's some confidentiality issues that might be  
17 -- might arise in that situation, but I'm sure  
18 there's a lot of smart people in this room that  
19 can help puzzle that out. I'm not that person,  
20 but I encourage you to pursue that. FDA experts  
21 knowledgeable with that prior approved drug should  
22 assist patent examiners in their review.

1                   These changes should expose patents  
2       filed simply to prevent or postpone generic  
3       competition. Third, better identification of  
4       conflicting statements by pharmaceutical  
5       applicants. You've already heard a lot about  
6       that. We think that this kind of double speak is  
7       probably hard for you to uncover. So, our  
8       recommendation is flagging applications which  
9       correspond to substantially similar drugs, sharing  
10      information given to both agencies, especially  
11      regarding clinical tests and spending more quality  
12      time reviewing to unearth those conflicting claims  
13      that might either signal an attempt to game the  
14      system or might simply just be mistakes.

15                  Fourth, clearly there's been a lot of  
16      finger pointing in this room about what data is  
17      true and what data isn't true. So, we need better  
18      database for the public and academic researchers  
19      to be able to utilize so that we can get to the  
20      source of some of these problems. If we have  
21      better information, regulators, researchers can do  
22      the work of looking at what the trends are and

1       understanding more about the patent system and  
2       identifying solutions to bring generics and  
3       biosimilars to market sooner. Fifth collaborative  
4       auditing and regulatory enforcement. We haven't  
5       really talked too much about enforcement today,  
6       but it seems like it would be great to collaborate  
7       between the two agencies on your different  
8       enforcement powers to share ideas and understand  
9       how you can support one another in the work that  
10      you're doing to oversee regulatory and statutory  
11      compliance.

12               Hopefully that's already happening, but  
13      if it isn't, that's a recommendation as well. And  
14      then we did spend a lot of time talking today  
15      about patient engagement. I'd like to underscore  
16      that too often policy solutions are proposed,  
17      analyzed and decided with hardly any consumer  
18      input. And when policymakers lose touch with the  
19      end user and in this case, I would say it's not  
20      the patent applicant or the FDA new drug  
21      applicant, but the public. Sometimes those  
22      consumer interests are put last.

1                   As a public interest advocate, I often  
2       walk into policy meetings with less technical  
3       knowledge than most, but I offer the valuable  
4       insight, as you've heard from others today, on the  
5       impact of your decisions by speaking from the  
6       perspective of an insured individual paying for  
7       health care or of a patient speaking about using  
8       health product services. So those are the values  
9       that you get from talking and involving consumers.  
10      I understand that there are more formal ways to  
11      engage consumers, but I think we all have in the  
12      room here some ideas on ways to better engage  
13      patients. Personally, I've worked with the  
14      National Quality Forum on a patient advisory  
15      council to better involve patients and consumers  
16      in their issues.

17                  The National Quality Forum does a lot of  
18      very highly technical quality measurement for  
19      hospitals and deciding which measures to use in  
20      the CMS star rating. And I'd be happy to share  
21      more learnings from that, but I think there's more  
22      room obviously to encourage patient involvement,

1       maybe in a less formal way. Thank you for your  
2       consideration of these ideas. We look forward to  
3       further collaboration with your collaboration.  
4       Thanks for this opportunity today to really talk  
5       about this and explore some meaningful  
6       recommendations.

7               JUDGE HORNER: Great. Thank you for  
8       your comments and for being here today. I'll turn  
9       it to the panel if we have questions. FDA  
10       questions? Ms. Till? Ali?

11              MS. TILL: You spoke about the patent  
12       misuse. Do you have examples of what that is --  
13       how you envision or what you believe that to be?

14              MS. KELMAR: So, I use that as a broad  
15       term to include what some here have said are, you  
16       know, misnomers or inflammatory language or  
17       something like that. But consumers and patients  
18       need a way to talk about these issues in more  
19       plain language. Right. We're not going to read  
20       long academic journals. So, things like patent  
21       thickets, that's something we can understand.  
22       It's many, many patents that are trying to block

1 competition that make it really hard to bring  
2 litigation to challenge patents. So, patent  
3 thickets, product hopping, these are some of the  
4 things that we've identified as consumers looking  
5 at the reasons that it's getting harder and harder  
6 to get generic drugs to market. And we're waiting  
7 longer and longer. Does that answer your  
8 question? Thank you.

9 MR. SALIMI: Hi. You spoke about the  
10 resources that we need to provide more resources  
11 to our examiners beside what we have already.  
12 What they are capable of in, what they are capable  
13 -- what they have as of now. What other resources  
14 do you know that we can provide to the examiners  
15 that they don't -- that they lack now, today?

16 MS. KELMAR: Well, I'm not the person in  
17 the room, so you all would be the better experts  
18 for that. I mean, I think it would be great to  
19 understand I don't know how much internal thought  
20 processes or gathering back of information, but it  
21 seems like doing these prior art searches are  
22 pretty difficult. And the complexities of working

1 with another agency that has a lot of the  
2 information that you might need is a difficult  
3 thing to do. So, if there's more time, I  
4 understand you're doing more training. Probably  
5 that is all helping.

6 But I would go to the examiners  
7 themselves and see how they can get help. And  
8 then there are other experts in this room who are  
9 closer to that, that, you know, a brainstorming  
10 session with them might be a great opportunity. I  
11 think it's just really hard for us to engage with  
12 the PTO, which has traditionally just been a much  
13 more buttoned down. There's three doors to enter  
14 and you have to fit in that door to be able to  
15 participate. So, a little more informal  
16 conversation might be a way to get the ball  
17 rolling.

18 MR. SALIMI: Just for the record, you  
19 might want to know that our examiners have access  
20 to the most sophisticated databases that exists,  
21 and they can find any article that gets published  
22 anywhere in the world, something that perhaps a

1 lot of people don't know. But we have a lot of  
2 tools available to the examiners. Now, I'm not  
3 saying that they're going to find exact order each  
4 and every time but given the time and everything  
5 else that they have, they have the most  
6 sophisticated databases available to them, perhaps  
7 absent Homeland Security or some of these other  
8 folks. And the Office spends a lot of money to  
9 maintain those, you know, to license those  
10 databases. Just for --

11 MS. KELMAR: I'm glad to hear that,  
12 thank you. And I -- it's an unenviable job, I'm  
13 sure, for patent examiners, especially when you're  
14 facing 600,000 applications a year. That's a lot.

15 JUDGE HORNER: Well, thank you again for  
16 being here. We're going to move on to our final  
17 speaker. We saved the best for last. Professor  
18 John Thomas from -- Jay Thomas from Georgetown  
19 University Law Center. You may begin when you're  
20 ready.

21 PROF. THOMAS: Thank you very much for  
22 having me here today. I observed that amongst the



1       seven government panelists, I have two former  
2       students, one at FDA and one at USPTO. So, I'm  
3       expecting some tough questions. It is my birthday  
4       today, so I ask for your forbearance. The whole  
5       of government approach affords the USPTO and FDA a  
6       long-delayed opportunity to revisit neglected  
7       opportunities to fulfill the goals of the  
8       Hatch-Waxman Act and encouraging pharmaceutical  
9       innovation while also promoting access to  
10      medicines. With these brief remarks, I focus upon  
11      the FDA publication known as the Orange Book.  
12      I've also provided more extensive written remarks  
13      with additional views.

14               Orange Book patent listings hold  
15      extraordinary consequences for public health.  
16      They allow brand name drug companies to sue  
17      generic firms for patent infringement, even though  
18      the generics have done nothing more than file an  
19      entirely accurate petition to the government  
20      asking for marketing approval. In such cases, FDA  
21      ordinarily may not approve the ANDA for 30 months.  
22      This 30-month stay effectively acts as a

1 preliminary injunction against the generic firm  
2 without requiring the patent proprietor to address  
3 the usual equitable factors or to post a bond.  
4 These incentives strongly encourage brand name  
5 drug companies to identify as many patents to the  
6 FDA as possible.

7           Numerous patents that fail to meet the  
8 statutory criteria have made their way into the  
9 Orange Book. Despite all of that, FDA has no  
10 oversight over the Orange Book. FDA simply lists  
11 in the Orange Book all identified patents without  
12 review. If a private party disputes the listing  
13 of a patent in the Orange Book, FDA merely informs  
14 the brand name drug company. Unless the brand  
15 name drug company withdraws or amends the patent  
16 information, FDA will not change the information  
17 in the Orange Book. FDA could do a much better  
18 job and at least take a rough initial look or  
19 perhaps a more substantive look to assess the  
20 propriety of Orange Book patent listings.

21           The agency should also provide for a  
22 more robust Orange Book listing challenges. FDA

1 plays no substantive role in current Orange Book  
2 listing challenges. The agency merely allows any  
3 interested person to provide it with a statement  
4 of dispute unless the brand name drug company  
5 withdraws or immunes its patent information in  
6 response to that dispute, FDA will not change the  
7 information in the Orange Book. A USPTO stands in  
8 a position to fill this gap. Administrative  
9 proceedings for the propriety of Orange Book  
10 listings could be conducted by the PTAB. But  
11 that's a determination that is well within the  
12 capability of APJs, as it's a paper-to-paper  
13 comparison between a patent and an ANDA. Those  
14 proceedings would comport with increased emphasis  
15 on administrative dispute resolution in the patent  
16 system, harness the considerable expertise of APJs  
17 in adjudicating adversarial proceedings and in  
18 view of the rapidly declining number of ex parte  
19 appeals to the PTAB, make use of available USPTO  
20 capacity.

21 Let me address my sort of final comments  
22 to the FDA's anomalous non statutory use code

1 practice. FDA does not assess the right to  
2 exclude afforded by a method of use patent in  
3 terms of the claim that the USPTO grants. Rather,  
4 FDA relies upon patent proprietors to paraphrase  
5 the scope of their claims, using 250 characters or  
6 less. FDA apparently did not establish the  
7 250-character limit following consultation with  
8 USPTO academics, jurists, anyone, as far as I can  
9 tell. Rather, FDA decided this highly condensed  
10 summary of complex legal texts granted by a peer  
11 agency was appropriate due to the size of a  
12 database fields and FDA's antiquated computer  
13 system. FDA has elevated use codes to the status  
14 of proprietary rights to which generic drug  
15 companies are accountable. If the use code  
16 indicates that the patent claims a method of use  
17 for which approval is sought, then the generic  
18 must submit an ANDA with either a paragraph three  
19 or paragraph four certification.

20 Otherwise, the generic applicant may  
21 submit a Section 8 statement. At the outset, FDA  
22 does not verify any of the submitted use code

1 information provided by brand name drug companies.  
2 It merely lists the use code and its accompanying  
3 narrative in the Orange Book. FDA's dispute  
4 resolution process with respect to use codes is  
5 also severely constrained. The relevant FDA  
6 regulation limits statements of disputes regarding  
7 use codes to 250 words directed to "the person's  
8 interpretation of the scope of the patent". FDA  
9 then forwards this information to the brand name  
10 drug company. Unless the brand name drug company  
11 withdraws or amends its patent information in  
12 response to this dispute. Then nothing happens to  
13 the use code. This anomalous non statutory use  
14 code practice for paraphrasing patents is so  
15 reductionist as to be absurd.

16 It results in broader intellectual  
17 property protection from brand name drug companies  
18 than Congress has allowed. It should be  
19 terminated immediately. FDA should read the  
20 claims of issued patents as the USPTO granted  
21 them, not in a summary and potentially  
22 self-serving form that may inaccurately portray

1 the scope of exclusivity they provide. If FDA  
2 remains unwilling to acquire sufficient experience  
3 or expertise to construe the legal text to which  
4 all members of the public are accountable and  
5 which were granted by a pure agency, then FDA  
6 ought to avail itself of USPTO resources as soon  
7 as possible. Thank you for the opportunity to  
8 submit these remarks.

9 JUDGE HORNER: Thank you, Professor  
10 Thomas. Open it up to the panel for a questions.  
11 Yes, go ahead.

12 MS. DAVIS: Thank you very much for your  
13 comments. Could you talk about if the FDA were to  
14 depart from its ministerial role and substantively  
15 weigh in on these patent disputes, how do you see  
16 it playing out then, if, say, the FDA decided one  
17 way or the other and then a company, whether it's  
18 the new drug applicant, the generic drug  
19 applicant, wanted to further challenge that,  
20 because I think normally these things play out in  
21 the courts and for example, as a counterclaim in  
22 patent litigation. So how would you see the

1 process playing out or how would you suggest it be  
2 structured if the FDA would --

3 PROF. THOMAS: Well, how the structure  
4 currently works is that FDA foists responsibility  
5 for policing the Orange Book upon the Federal  
6 Trade Commission or private antitrust enforcers.  
7 So that's where we are right now. If you looked  
8 at it, my sense is there would just be less abuse  
9 of the Orange Book because individuals wouldn't  
10 want to test that. But I think where you're going  
11 and it's true, you would be subject to litigation  
12 in the District Court for the District of  
13 Columbia.

14 JUDGE HORNER: That was kind of -- Oh,  
15 I'm sorry. Go ahead.

16 MS. DAVIS: Just to clarify so that then  
17 the recourse would be to the courts. Is that how  
18 you would see it playing out?

19 PROF. THOMAS: If an entity disagreed  
20 with -- if a brand name drug company disagreed  
21 with your decision not to list a patent in the  
22 Orange Book, then that they would have the

1 opportunity to sue you essentially, yes.

2 MS. TILL: Okay. So, my question kind  
3 of leans into that as well, because your other  
4 alternative was to have APJs make these  
5 determinations as to whether a patent was properly  
6 listed or not. But the listing is not under a  
7 patent statute. So, if APJs were to do that  
8 procedure, what if the brand company disagreed?  
9 What would be the remedy?

10 PROF. THOMAS: Okay, so let's be quite  
11 clear about this. The Orange Book has been  
12 littered with patents on tablets, shapes and  
13 scoring, containers. There's a litigation going  
14 on right now with a REMS computer system listed in  
15 the Orange Book. So don't think that these -- the  
16 FDA's task may be simpler than you seem to be  
17 letting on. It's not always a very complex  
18 determination, but right now it's just these  
19 patents go into the into the Orange Book and  
20 there's just no oversight. And they block generic  
21 competition by the automatic action of a statute.

22 So, again, APJ's could be detailed to



1       FDA. There's a lot of trust between your agencies  
2       in terms of different and there could be more. Or  
3       alternatively, the FDA could simply hire a patent  
4       attorneys. FDA currently has patent attorneys on  
5       its staff. It used to write the use codes itself,  
6       and then for some reason you stopped and left it  
7       to the responsibility of self-interested brand  
8       name drug companies. So, but yes, so those are  
9       the opportunities the FDA could revert to its  
10      former practice of writing the use codes or FDA  
11      could supervise use codes that are submitted by  
12      Orange Book patent listers.

13               JUDGE HORNER: Thank you. I think in  
14      the interest of --

15               MS. TILL: Can I ask one more question?

16               JUDGE HORNER: Oh, one more question.

17               MS. TILL: Sorry. So, if the use code  
18      practice was --

19               PROF. THOMAS: She's one of the former  
20      students, you know, that's --

21               MS. TILL: -- completely eliminated.

22               PROF. THOMAS: The tables are turned.

1 I'm sorry, Mary.

2 MS. TILL: If the use codes were  
3 completely eliminated, what would be a sort of  
4 alternative practice to informing the public  
5 and/or any potential and a filer of the particular  
6 claims in a patent that relate to a method of use?

7 PROF. THOMAS: Well, shockingly enough,  
8 the warning would be the patent claims as the  
9 agency actually issues them. I probably couldn't  
10 get fired from Georgetown University for doing  
11 almost anything, but I certainly wouldn't -- I  
12 don't tell my students that they should be reading  
13 250-character abstracts of what, more than 100  
14 claims in a patent. Again, it would be more  
15 rational for FDA to look at the abstract of a  
16 patent than a use code.

17 No patent attorney would ever tell you  
18 that the abstract of a patent sets forth its  
19 exclusive rights, but at least the abstract was  
20 read by USPTO. It often parrots claim one of the  
21 patent, and it's got like 150 to 250 words.  
22 That's the standard on the MPEP. That's at least

1 better than that of 250-character use code, which  
2 again is it's non statutory. This practice really  
3 needs to stop as soon as possible. It's absurd.

4 JUDGE HORNER: Thank you. Go ahead.

5 MS. TERROT: I did have one question.  
6 Are you proposing new statutory provisions to  
7 provide a basis for FDA to construe the claims,  
8 assess the scope of the patents to verify  
9 listings, or do you believe that authority exists  
10 in current law?

11 PROF. THOMAS: Every member of the  
12 public and the government is responsible for each  
13 claim in every issued patent that this agency puts  
14 out. And that includes the FDA. You don't need  
15 any statutory authorization. You should read the  
16 patents as your peer agency grants them and not  
17 wholly disregard them. There is no statutory  
18 provision needed one way or the other. You're the  
19 ones who have come up with this non statutory  
20 practice, which is just not the way anyone else in  
21 the universe reads patents and it's prone to  
22 abuse.

1                   JUDGE HORNER: Okay. Thank you for your  
2                   comments, for being here, and for your input.  
3                   This concludes Session five. But before we wrap  
4                   up, I'm going to invite Deputy Director Derrick  
5                   Brent to make his way to the podium at the front  
6                   of the room for some closing remarks. And while  
7                   he does that, I'm going to give him a brief  
8                   introduction. Derrick Brent is the Deputy  
9                   Undersecretary of Commerce for Intellectual  
10                  Property and the Deputy Director of the United  
11                  States Patent and Trademark Office.

12                 His responsibilities include working  
13                 with Director Vidal to lead the agency advance IP  
14                 policy for the benefit of the country and expand  
15                 the USPTO outreach efforts to incentivize and  
16                 support more innovation and entrepreneurship  
17                 nationwide and execute the agency's policies,  
18                 priorities and programs. Director Brent's career  
19                 includes vast public service and private sector  
20                 work, including significant experience in IP law  
21                 and work to assist startups, as well as those who  
22                 are underrepresented.

1           He served for six years as chief counsel  
2     for Senator Barbara Boxer. He also clerked for  
3     the Honorable Algenon L. Marbley, Chief Judge of  
4     the United States District Court for the Southern  
5     District of Ohio. After litigating at the law firm  
6     of Vorys, Saters, Seymour and Pease in Ohio, he  
7     served six years as a senior trial attorney at the  
8     U.S. Department of Justice Civil Rights Division,  
9     where he received a special achievement award for  
10    his trial work. Deputy Director Brent has also  
11    served in the private sector as vice President and  
12    Associate General Counsel for the multinational  
13    medical technology company, Masimo. I invite you  
14    to deliver some closing thoughts.

15           DEPUTY DIRECTOR BRENT: Turned -- it  
16    turned on. I was so used to all day looking at  
17    the microphones around and seeing the red light  
18    on, telling me that they worked. Then when I  
19    looked down and saw the red light that I actually  
20    thought this was a hot mic. So, and I've been  
21    trained for my days in the Senate to be careful  
22    around hot mics and had to dive across the senator

1 a few times to hit the mic button. I want to  
2 start off by thanking Linda. I want to thank all  
3 of the PTO staff, all of the FDA staff for their  
4 hard work and putting on an excellent listening  
5 session discussion.

6 It was a great conversation that was had  
7 here, and that's why I don't call it testimony or  
8 anything. It was really conversation because it  
9 was a truly an exchange. And I'm looking forward  
10 to as we go forward and hopefully this is the, I'm  
11 not going to say hopefully, I know it is the first  
12 of other sessions that we will conduct in order to  
13 better reach more understanding and to help find  
14 ways to make progress and work together. I also  
15 want to thank the patient advocates and the other  
16 speakers who came out today. Your time, your  
17 dedication combined with the hard work of the  
18 staff, putting this on help to make this a  
19 success.

20 And again, it's only one step and we  
21 have more to do. You know, I was -- a few years  
22 ago, I was interviewed by a former intern of mine

1       who was in law school. And she asked me an  
2       interesting question. She said, what was the life  
3       lesson that is served you well throughout your,  
4       you know, throughout your career? And I had to  
5       think thought about all my various sports coaches  
6       and my various teachers who yelled at me for  
7       different things because that's how lessons are  
8       learned. Right. But more importantly, I  
9       remembered something that was said, and I  
10      responded to her and I said, only through dialogue  
11      can we reach understanding.

12               And it's a comment that Director Vidal  
13      has repeated a few times to me. She really liked  
14      it. And by the way, I'd be remiss if I didn't  
15      thank if I didn't thank Director Vidal, as well as  
16      the FDA Commissioner Califf, for their leadership  
17      in getting this not only the working group  
18      together, but also providing the resources to make  
19      this conversation and these exchanges happen, and  
20      also the work that still will be -- that is still  
21      to be done, but only through dialogue can we reach  
22      understanding.

1                   That's where we talk and we listen. And  
2           today was an example of that type of work, and  
3           it's the work we have to do. The other thing that  
4           this event showed today was that the work of the  
5           PTO and the FDA goes well beyond approval, denial  
6           and registration, simple administrative tasks. It  
7           reaches into the marketplace, but more  
8           importantly, it reaches into it reaches into the  
9           lives of people, the very people that we are sworn  
10          to serve. So, in conclusion, I say let's keep the  
11          conversation going. Let's keep the work going.  
12          There's more to do and there's better to do.  
13          Thank you for your time.

14                   JUDGE HORNER: Thank you. This  
15          concludes our Listening Session. I would just like  
16          to thank our logistics team behind the scenes who  
17          put this whole event together. Starr Baker, Lorrie  
18          Jenkins, Rhonda Corbin, Alan Cogswell, Cheryl  
19          DaSilva and LaShawn Fortune. They put a lot of  
20          hard work in to make this run as smoothly as it  
21          did today, and we appreciate their efforts. Thank  
22          you, everyone.



1 (Whereupon, at 4:20 p.m., the  
2 PROCEEDINGS were adjourned.)

3 \* \* \* \* \*

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

## 1 CERTIFICATE OF NOTARY PUBLIC

## 2 COMMONWEALTH OF VIRGINIA

3 I, Mark Mahoney, notary public in and for  
4 the Commonwealth of Virginia, do hereby certify  
5 that the forgoing PROCEEDING was duly recorded and  
6 thereafter reduced to print under my direction;  
7 that the witnesses were sworn to tell the truth  
8 under penalty of perjury; that said transcript is a  
9 true record of the testimony given by witnesses;  
10 that I am neither counsel for, related to, nor  
11 employed by any of the parties to the action in  
12 which this proceeding was called; and, furthermore,  
13 that I am not a relative or employee of any  
14 attorney or counsel employed by the parties hereto,  
15 nor financially or otherwise interested in the  
16 outcome of this action.

17

18 (Signature and Seal on File)

19 Notary Public, in and for the Commonwealth of  
20 Virginia

21 My Commission Expires: August 31, 2025

22 Notary Public Number 122985

