



The Honorable Andrei Iancu
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Madison Building,
600 Dulany Street
Alexandria, VA 22314

June 4, 2018

Dear Director Iancu,

The Initiative for Medicines, Access & Knowledge ([I-MAK](#)) is a not-for-profit team of lawyers, pharmaceutical scientists and health experts working to improve the patent system for families struggling to access the medicines they need. We founded I-MAK in 2006 and have successfully prevented unmerited pharmaceutical patents from keeping lifesaving medicines out of reach of patients worldwide. Our multi-state and global team is comprised of individuals who left careers in the private sector – including the pharmaceutical industry and private legal practice - to dedicate themselves to the task of reducing drug prices through active participation in the patent system.

Today, 1 in 4 American families reports difficulty in filling a prescription due to skyrocketing drug prices, and 80% of Americans across the political spectrum are calling for change. Our first-hand experience working on thousands of drug patents over the last decade has revealed an evidence base of overpatenting practices. From continuation applications to the proliferation of patents designed to improperly extend exclusive rights on products, this gaming of the patent system is directly linked to the crippling of state health budgets and the struggles of working families.

I-MAK works to ensure that households get the medicines they need by ensuring the voices of patients and families are heard and represented within the patent system. We do this by actively participating in patent challenge mechanisms, working to increase transparency to improve patent quality through patent offices worldwide, increasing public education about the patent system and its critical relationship to drug prices, and providing thought leadership on key health safeguards for patent law and policy that promotes access and genuine inventiveness.

Given our unique expertise regarding the impact of unmerited pharmaceutical patents for patients, we write to offer our perspective on matters of USPTO policy. While our work is predicated on how future USPTO policies could impact the ability of working families to be able to afford medicines, our inputs will be strictly legal and technical in nature.

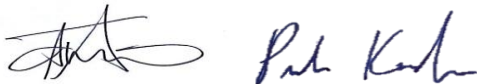
Based on reports and transcripts of public hearings and interviews given to date, we understand as Director of the USPTO you intend to bring clarity and predictability on issues concerning patentable subject matter and review procedures for challenging granted patents. We set out below our general thoughts on these two issues as they relate to the issue of drug pricing, and welcome the opportunity for ongoing dialogue.

Patentable Subject Matter. In recent years, the Supreme Court has issued several decisions regarding patent eligible subject matter. Two of the cases, *Mayo Collaborative Services v Prometheus Laboratories (2012)* and *Association for Molecular Pathology v Myriad Genetics (2013)*, related to medical technologies. In particular, these cases specifically dealt with personalized medicine where a patient's treatment was dictated by either that particular patient's response to a pharmaceutical or genetic code. The Supreme Court expressed that the concerns of industry being able to obtain patents on natural laws or phenomena must be balanced with those of the public interest. Implementing the patentable subject matter balance struck by the Supreme Court may be difficult, but it is important to ensure that patents not be issued which would be harmful to the American people.

PTAB. As we noted last month in an [op-ed in the Hill](#), "The PTAB can curb abuse and help restore integrity to our patent system, stopping drug companies from holding a wrongly issued exclusive right for years or even decades more." I-MAK is an active participant in the *inter partes* review process to challenge patents on lifesaving medicines that are being priced out of reach for everyday Americans. Changes to PTAB practice will thus have a direct impact on I-MAK and its ability to ensure working families are able to afford medicines that may currently be held out of reach by questionable patents. While ensuring the process is fair to patent holders and petitioners alike, the process should continue to fulfill the intent behind the creation of IPRs, which was to provide a quick and efficient process for cancelling unmerited patent claims.

In closing, we here at I-MAK stand ready to assist you in any way we can in developing and implementing changes to USPTO policy and practice. We aim to help the USPTO achieve its goal of promoting scientific progress while not issuing or maintaining undeserved pharmaceutical patents. Families across America are counting on the USPTO to weed out unmerited patents and enable a fair and competitive marketplace.

Sincerely,

Handwritten signatures of Tahir Amin and Priti Krishtel in black ink.

Tahir Amin and Priti Krishtel

Initiative for Medicines Access & Knowledge (I-MAK)