Founders’ Letter

For 11 years, I-MAK has worked to solve the drug patent problem worldwide so that individuals with life-threatening diseases are able to live healthy lives. The movement to fight for the rights of patients emerged twenty years ago in the face of unconscionable prices for medicines to treat diseases that affect our world’s most impoverished citizens. In recent years, outrage over rising drug prices has spread from lower-income countries to wealthier ones. While there has been significant progress, the work is not complete. Today, patients from across the world from varied social, political, and economic backgrounds are making their voices heard: drug prices must decrease. At the heart of this is an urgent need for a more equitable economic system.

Families today are being forced to make unimaginable choices when it comes to getting medicines they need, and this disproportionately impacts households that are struggling to make ends meet. To illustrate, in the five years since the cure for hepatitis C was approved for use in patients, only 3 million of the 71 million people living with chronic hepatitis C are receiving it due to exorbitant pricing. In the U.S., where treatment launched at up to $1,000 per pill (while identical generic equivalents cost less than $5 per pill), 85% of people who have been diagnosed with hepatitis C are not receiving treatment, and new cases are increasing at unprecedented rates due in large part to the opioid epidemic.

In the past four years, I-MAK has supported ten cases around the world on hepatitis C drugs. Of these, four countries have already rejected patents on the drug sofosbuvir, paving the way for competition and a new hope for families waiting for treatment for loved ones. Hoping to replicate these successes and ensure that patients do not have to wait a decade or longer for life-saving treatment, I-MAK sparked national attention in 2017 by filing the first public interest patent challenges against Gilead Sciences’ hepatitis C drugs in the U.S. Our team of talented and passionate legal, scientific, and policy experts investigated and exposed pharmaceutical companies’ tactics and informed the American public of these injustices at the expense of their health and financial security.

Despite burgeoning outrage at the skyrocketing prices of medicines, policymakers around the world have not met these emerging challenges with bold and impactful solutions. The role of civil society has expanded to find solutions in the interim. Together with our partners, I-MAK has played a leading role in defining and executing those solutions worldwide.

Today, we are laying the groundwork to transform patent systems so that future generations will live in a world where the price of medicines is rooted in health and economic equity, fairness, and justice for all. When the pharmaceutical industry can no longer rely on an expansion and abuse of monopolies to charge unaffordable prices, the transformation we collectively seek – a world where all patients receive the treatments they need to live healthy lives – will be possible.

Determined as ever, we look forward to the new challenges and opportunities that lay ahead.

—

Priti Krishtel & Tahir Amin
Co-Founders / Co-Executive Directors

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**I-MAK is solving the drug patent problem**

People worldwide – including in the U.S. – are not receiving the lifesaving treatment they need due to skyrocketing drug prices. All too often, drug companies apply for unmerited patents to block competition. When these and other anti-competitive strategies are successful, a company can corner the market, artificially inflate the price of treatment, and block access to affordable medicines for decades.

Our mission is to increase global access to affordable life-saving medicines by restoring integrity to the patent system. I-MAK’s team of lawyers, scientists, and health experts quit their lucrative careers in the private sector to solve this problem. Taking an evidence-based approach, we work to shed light on the pharmaceutical industry’s abuse of the patent system and remove barriers to treatment for high burden diseases such as the hepatitis C virus (HCV), HIV, cancer, and blood-related disorders.

We aim to transform the pharmaceutical industry through strategic influence and legal action to address the root causes of high cost treatments. Each of our programmatic areas supports I-MAK’s vision for a patent system that serves the public and creates a competitive market.

**Short-term vision:**
Challenging unmerited patents in order to accelerate access to lifesaving medicines.

**Medium-term vision:**
Fixing the patent system to protect and promote the interests of patients.

**Long-term vision:**
Developing equitable incentive models that prioritize people’s access to affordable treatment.

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**DATA & METRICS**
Providing evidence-based, data-driven research and analysis. We analyze the connection between patents and drug prices to reveal the anti-competitive strategies used by branded pharmaceutical companies and the cost to our society. This enables our team of lawyers to make informed decisions about which patents to challenge, provides decision-makers with key data, and educates the public on the link between patents and high drug prices.

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**COMMUNICATIONS**
Educating the public globally. Through our public education efforts, we put industry abuse in the public eye. Educating the public on pharmaceutical industry tactics that directly impact their right to affordable treatment is key to building demand for policy reform.

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**STAKEHOLDER ENGAGEMENT**
We influence stakeholders including government, civil society, and people affected by these diseases to create systems that support a competitive market where the needs of patients and purchasers come first.

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**POLICY SOLUTIONS**
Fighting to reform patent policy worldwide. We advocate for a coordinated approach by policymakers, health advocates, purchasers, and consumers to demand a system that is more open and accessible to patients and the public. This includes laws and policies that allow for public participation, generate competition to drive down prices as well as strengthening criteria for how monopoly rights are granted.

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**STATEGIC PATENT CHALLENGES**
Filing patent challenges to get millions of people lifesaving drugs. Based on data exposed through our investigations and research, we file cases against patents that do not comply with the law’s requirements.

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**GENERATING EVIDENCE**
Creating transparency to guide strategy. We create information transparency about intellectual property for drugs and diseases to strengthen the global health community’s ability to quickly determine how to maximize drug access. This includes mapping all relevant patents for a particular drug by country, and assessing whether legal challenges or other strategies should be pursued to create a pathway for generics.
"We appreciate I-MAK’s strategic legal analysis and recommendations, which have provided guidance to increase access to HIV prevention for people across Europe. Their relentless dedication to the access to medicines movement is why we are proud to partner with them.”

JORRIT KABEL
POLICY ADVISOR, AIDS FONDS

From 2014 to 2018, I-MAK worked alongside five patient advocacy organizations as a member of the Make Medicines Affordable Consortium. Legal interventions on seven HIV drugs in Argentina, Brazil, Thailand, and Ukraine have reduced prices and have saved health systems US$472 million per year.

"I-MAK’s 2017 report on America’s Overspending provided extremely compelling data regarding the need for patent reform to prevent evergreening. Here in South Africa, we’re using these findings to fuel our fight with HIV-positive and cancer patients to take on the government to fix the patent laws”

CATHERINE TOMLINSON
STEERING COMMITTEE MEMBER OF FIX THE PATENT LAWS, CANCER ALLIANCE, SOUTH AFRICA

"Our global presence

Over the past decade, I-MAK has filed or technically supported legal action against 39 unmerited patents behind six major HCV and HIV drugs across significant markets worldwide. We have an 80% success rate in cases that have reached a decision.”

CHALERMSAK KITTITRAKUL
PROGRAM MANAGER, AIDS ACCESS FOUNDATION (THAILAND)

Lorena Di Giano, a female human rights lawyer and the executive director of Fundación Grupo Efecto Positivo, is working with I-MAK to increase access to affordable generic treatments to address her country’s HCV crisis. With I-MAK’s legal support, her organization prevented a secondary patent on the HCV drug sofosbuvir from being granted through a successful patent challenge in May 2015; and subsequently filed a challenge on the base compound in February 2017.

Due to Lorena and FGEF’s perseverance in fighting the pharmaceutical lobby, local production of generic sofosbuvir will now have a direct impact on the lives of those with HCV.

"I-MAK’s patent oppositions and reports for key HIV drug patents provided ABA with evidence and arguments to ramp up our fight for access to lifesaving medicines in Brazil. We are proud to work in partnership with I-MAK to continue the global fight to improve the patent system and ensure the right to health is a reality for all people.”

VERIANO DE SOUZA TERTO,
VICE PRESIDENT, THE BRAZILIAN INTERDISCIPLINARY AIDS ASSOCIATION (ABA)

"As a result of I-MAK’s successful patent challenges on four HIV drugs in India, prices for these lifesaving generic medicines are now 51-89% lower than the branded versions. These wins have helped supply low- and middle-income countries worldwide with low-cost generics, saving an estimated US$500 million – money that could be reinvested to treat more than one million people.

CHALERMSAK KITTITRAKUL
PROGRAM MANAGER, AIDS ACCESS FOUNDATION (THAILAND)

"I-MAK has been fighting to reform the patent system for over a decade worldwide and brings their experience to fight for the rights of people living with HIV in Ukraine.”

SERGIY KONDRAITYUK
LEGAL SPECIALIST ON ACCESS TO TREATMENT, ALL-UKRAINIAN NETWORK OF PLWH

"Working together with I-MAK has enabled us to propose language to amend the patent law in Ukraine to support the public health, and file patent challenges to lower HIV drug prices in Ukraine. I-MAK has been fighting to reform the patent system for over a decade worldwide and brings their experience to fight for the rights of people living with HIV in Ukraine.”

VERIANO DE SOUZA TERTO,
VICE PRESIDENT, THE BRAZILIAN INTERDISCIPLINARY AIDS ASSOCIATION (ABA)

"The I-MAK Roadmap Report opened game-changing conversations with the government and allowed us to get transparency on patent information that enabled us to determine strategy. Our organization of Thai People Living with HIV is focusing on getting this lifesaving HIV treatment on Thailand’s essential medicines list, which will enable access to those that need it.”

CHALERMSAK KITTITRAKUL
PROGRAM MANAGER, AIDS ACCESS FOUNDATION (THAILAND)

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CHALERMSAK KITTITRAKUL
PROGRAM MANAGER, AIDS ACCESS FOUNDATION (THAILAND)
In 2017, I-MAK filed its greatest number of patent challenges in a single year through the hard work of its results-oriented, impact-driven team. We filed 15 new patent challenges against two pharmaceutical companies.

**The Potential Ripple Effect**

In China, it is estimated that there are 10 million people living with HCV.

- **Sofosbuvir** (Gilead Sciences): Crystalline compound
- **Velpatasvir** (Gilead Sciences): Base compound
- **Daclatasvir** (Bristol-Myers Squibb): Intermediate compound

China serves an essential role in the global pharmaceutical drug supply chain, manufacturing more than 800,000 tons of pharmaceutical ingredients each year. More than 70% of all active drug materials consumed in the U.S. and Europe are imported from China and India. Removing the barriers of unjustified patents in these countries will open up the supply of raw materials to manufacturers and increase the production of generic treatments for three major cancer and hepatitis C drugs, patients and taxpayers will pay more than US$50 billion in excess costs.

**Potential impact:**

$138USD if only 15% of people with HCV are treated

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**United States**

In the U.S., it is estimated that there are more than 3.5 million people living with HCV, and only half are diagnosed.

85% of those diagnosed with chronic HCV in America will not receive treatment this year. Reliance on prescription opioids has led to the recent resurgence of this disease, accelerating transmission across America. Gilead Sciences has claimed ownership of Sovaldi®, enabling the company to reap over US$55 billion in worldwide sales and set records for the fastest drug to achieve commercial ‘blockbuster’ status. In the interest of increasing their profit margin, Gilead Sciences is blocking those infected from receiving affordable treatment by proliferating unmerited patents.

In October of 2017, I-MAK filed the first public interest patent challenges in the U.S. against Sovaldi® at the U.S. Patent and Trademark Office, arguing that the drug’s eight core patents do not meet the legal standards for novelty and non-obviousness.

We also wrote a report exposing the pharmaceutical industry’s patent abuse, explaining how these tactics are driving up the cost of America’s most expensive and widely used prescription drugs. We found that as a result of tactics used to delay competition of generic treatments for three major cancer and HCV drugs, patients and taxpayers will pay more than US$50 billion in excess costs.

We are actively calling for reform of the patent system and keeping the public informed of how pharmaceutical patent abuse affects their lives. In 2017, we published four opinion editorials educating the public on patent abuse. In addition, we were quoted in multiple major publications as experts transforming the patent system.

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**India**

In India, it is estimated that there are approximately 18 million people living with HCV.

In partnership with the Delhi Network of Positive People (DNP+) and Médecins sans Frontières (MSF), I-MAK filed four patent challenges on HCV treatments:

- **Sofosbuvir** (Gilead Sciences): Crystalline compound
- **Velpatasvir** (Gilead Sciences): Base compound
- **Daclatasvir** (Bristol-Myers Squibb): Intermediate compound
- **Daclatasvir** (Bristol-Myers Squibb): Crystalline form

In partnership with the Network of Positive People (NAPL), I-MAK filed four patent challenges on HCV treatments. This will ultimately create a positive ripple effect around the world by increasing the affordable supply of drugs to millions of patients who currently cannot get the medicine they need to survive.
Financials

Between 2016 and 2017, I-MAK experienced 133% growth and more than doubled our total operating budget. Our spending continues to be program-focused with only 17% General and Administration expenses, which were necessary to build organizational capacity to absorb increased revenue, staff, and programmatic work.

OPERATING SUPPORT & REVENUE SOURCES

<table>
<thead>
<tr>
<th>Source</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contributions and Grants</td>
<td>$2,520,116</td>
<td>$2,526,890</td>
</tr>
<tr>
<td>Program Service Revenue</td>
<td>$6,775</td>
<td>$6,775</td>
</tr>
<tr>
<td>Total operating support and revenue</td>
<td>$2,526,890</td>
<td>$2,526,890</td>
</tr>
</tbody>
</table>

PROGRAM & OPERATING EXPENSES

<table>
<thead>
<tr>
<th>Expense</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Services</td>
<td>$1,479,783</td>
<td>$1,868,967</td>
</tr>
<tr>
<td>General and Administrative</td>
<td>$323,154</td>
<td>$323,154</td>
</tr>
<tr>
<td>Development and Fundraising</td>
<td>$66,029</td>
<td>$66,029</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>$1,868,967</td>
<td>$1,868,967</td>
</tr>
</tbody>
</table>

Total assets: $781,794
Total liabilities: $39,678
Net assets or fund balances: $742,116

Partners

I-MAK collaborates with global health organizations, governments, civil society organizations, academics, and technical experts to improve access to medicines worldwide.

These collaborations not only increase the number of people on life-saving medicines in these countries, but also strengthen local capacity to ensure continued access.

FUNDING PARTNERS

- AIDS Fonds
- Calamus Foundation
- Laura and John Arnold Foundation
- Médecins Sans Frontières
- Open Society Foundations
- UNITAID

GLOBAL PARTNERS

- “In the access to medicines movement, I-MAK has played an invaluable role as a pioneer and global leader in advancing access to lifesaving medicines by skilfully challenging unmerited patents. Their commitment to working alongside communities and sharing their expertise with others has inspired and helped build capacity of other civil society organizations around the world to apply the same approach.”

  AZZI MOMENGHALIBAF
  SENIOR PROGRAM OFFICER, OPEN SOCIETY FOUNDATION

- “We are proud to be long-term partners with I-MAK. Our relationship with I-MAK has enabled us to bring fresh vision and energy to the fight for affordable treatment for all people worldwide. I-MAK has worked closely with us to understand the needs of HIV-positive communities around the world and has fought to make affordable treatment a reality for many people.”

  OTTHMAN MELLOUK
  LEAD FOR INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES, INTERNATIONAL TREATMENT PREPAREDNESS COALITION

- “There is little debate that the market for pharmaceuticals is broken, and abuse of the patent system is a major driver of the problem. Companies like Gilead employ teams of lawyers to exploit the letter and spirit of patent laws, extending drug monopolies and keeping prices artificially high.”

  JOHN ARNOLD
  CO-CHAIR OF THE LAURA AND JOHN ARNOLD FOUNDATION
I-MAK plays a critical role in the civil society movement to increase access to lifesaving medicines.

What makes I-MAK stand out is that they’ve helped break the glass ceiling that lawyers alone can deal with patent issues, and they’ve fought hard to ensure that the voices of communities are heard.

SOLANGE BAPTISTE
EXECUTIVE DIRECTOR, INTERNATIONAL TREATMENT PREPAREDNESS COALITION
I-MAK’s Board of Directors

Since its founding, I-MAK’s voluntary Board of Directors has been composed of donors, academics, and practitioners in patent law, philanthropy, and business design.

Amanda Parsons  Vice President, Community & Population Health at Montefiore Health System
Lara Galinsky  Executive Coach & Entrepreneur in Residence, Future Laboratories LLC
Reena Abraham  Vice President of Education Programs at Local Initiatives Support Corporation
Renu Saini  Program Officer, Walton Family Foundation
Monica Mehta  Clinical Pharmacist in Infectious Diseases at New York-Presbyterian Hospital/Columbia University Medical Center
Priti Krishtel  Co-Founder & Co-Executive Director
Tahir Amin  Co-Founder & Co-Executive Director
David Watson  Emeritus

Our Team

I-MAK’s team is comprised of senior attorneys, scientists, and health experts who have worked to lower drug prices for 15 years.

Tahir Amin  CO-FOUNDER & CO-EXECUTIVE DIRECTOR
Nini Hoang  ADMINISTRATIVE ASSISTANT
Dan Ravicher  U.S. PATENT COUNSEL
Rohit Malpani  SPECIAL ADVISOR, PATENT LAW AND POLICY
Aaron Pattillo  MARKET DYNAMICS
Farzana Fakhry  MANAGER, FINANCE & ADMINISTRATION
Nina Hoang  ADMINISTRATIVE ASSISTANT
Dana Gill  EXTERNAL AFFAIRS
Priti Krishtel  CO-FOUNDER & CO-EXECUTIVE DIRECTOR
Joe Fortunak  PHARMACEUTICAL SCIENTIST / INNOVATOR
Martine Holston Hughey  SCALING PARTNER / GROWTH ARCHITECT
Rohit Malpani  SPECIAL ADVISOR, PATENT LAW AND POLICY
Priti Krishtel  CO-FOUNDER & CO-EXECUTIVE DIRECTOR

“I-MAK has helped bring transparency to the patent system through empirical research showing how companies game the patent system to extend their monopolies and advising on best practices for patent offices worldwide in relation to public health. I-MAK is helping to foster a growing movement of advocates working together to challenge the status quo.”

AZZI MOMENGHALIBAF  SENIOR PROGRAM OFFICER, OPEN SOCIETY FOUNDATION

“Working together, FGEP and I-MAK challenged unmerited patents standing in the way of patients accessing affordable hepatitis C treatments in Argentina. FGEP is proud to partner with I-MAK: they work alongside us with shared principles and values to ensure that we can curb rampant abuses of the pharmaceutical industry that block lifesaving medicines.”

LORENA DI GIANO  EXECUTIVE DIRECTOR, FUNDACIÓN GRUPO EFECTO POSITIVO, ARGENTINA
Join our movement!

I-MAK seeks support from those who believe that a world is possible where all people have access to affordable lifesaving treatments. We do not accept funding from branded or generic pharmaceutical companies in order to stay independent and exclusively represent the interests of patients and consumers.

Help us make lifesaving drugs accessible to all
Donate today by visiting our website: i-mak.org/donate

Tax Exempt Status
I-MAK is a not-for-profit 501(c)3 charitable organization and all contributions to I-MAK are 100% tax deductible.

Want to join us?
Please contact us at development@i-mak.org

Follow us on Twitter
@imakglobal

Visit our website: i-mak.org