



Annual Report 2017



Solving the drug patent problem

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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



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.





make
medicines
affordable
END UNFAIR MONOPOLIES

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.

"We appreciate I-MAK's strategic legal analysis and recommendations, which has 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

"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."

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

"I-MAK's 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)

"I-MAK's patent oppositions and reports for key HIV drug patents provided ABIA 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 (ABIA)

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.

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.

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 FGEP'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 2017 report on America's Overspend 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"

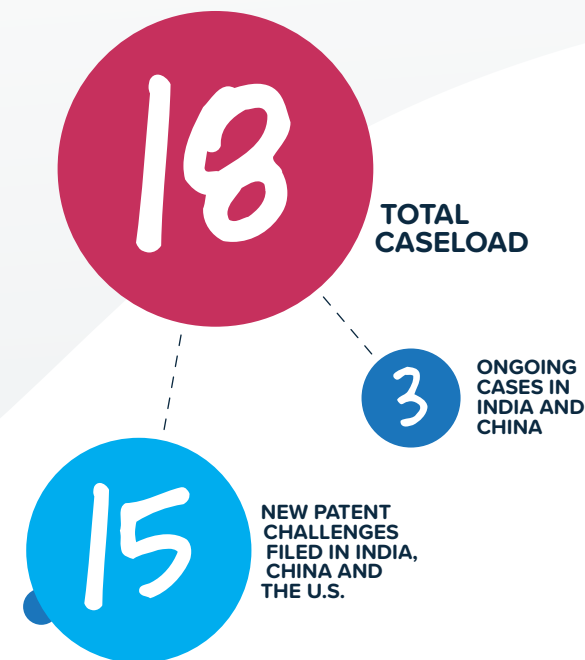
CATHERINE TOMLINSON
STEERING COMMITTEE MEMBER OF FIX
THE PATENT LAWS, CANCER ALLIANCE,
SOUTH AFRICA

Our global presence

KEY SUPPORTED CASES DIRECTLY FILED CASES

2017ⁱⁿ Review

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.



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): Crystalline form
- **Daclatasvir** (Bristol-Myers Squibb): Intermediate

China

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

I-MAK filed a legal challenge against Gilead Sciences' remaining patent for sofosbuvir (base compound). The 2017 filing follows another legal challenge filed by I-MAK in 2015, which resulted in China's State Intellectual Property Office (SIPO) rejecting a critical patent application on sofosbuvir (currently under appeal by Gilead).

Potential impact:

\$13BUSD if only 15% of people with HCV are treated

The Potential Ripple Effect

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. 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.

United States

OCT 2017 WHITE PAPER:

AMERICA'S OVERSPEND: HOW THE PHARMACEUTICAL PATENT PROBLEM IS FUELING HIGH DRUG PRICES

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.

Bloomberg

Gilead's Patents on Hepatitis C Drug Challenged by Consumer Group

"The Initiative for Medicines, Access & Knowledge, a nonprofit focused on how patents..."

THE LANCET

Patents, Licenses and Drug Prices

"This is one of the fundamental problems as to why we are seeing drug prices so high is..."

The New York Times

Patent 'Trolls' Recede as Threat to Innovation. Will Justices Change That?

"In a brief to the court, I-MAK – a non-profit group arguing for broader access to..."

STAT

Gilead faces challenge to U.S. hepatitis C patents from advocacy group

"In the latest attempt to attack the cost of hepatitis C drugs, an advocacy group is challenging..."

Newsweek

There is only one sure way to fix the hepatitis C epidemic

"The consequences of the exorbitant price of hepatitis C medication are dire..."

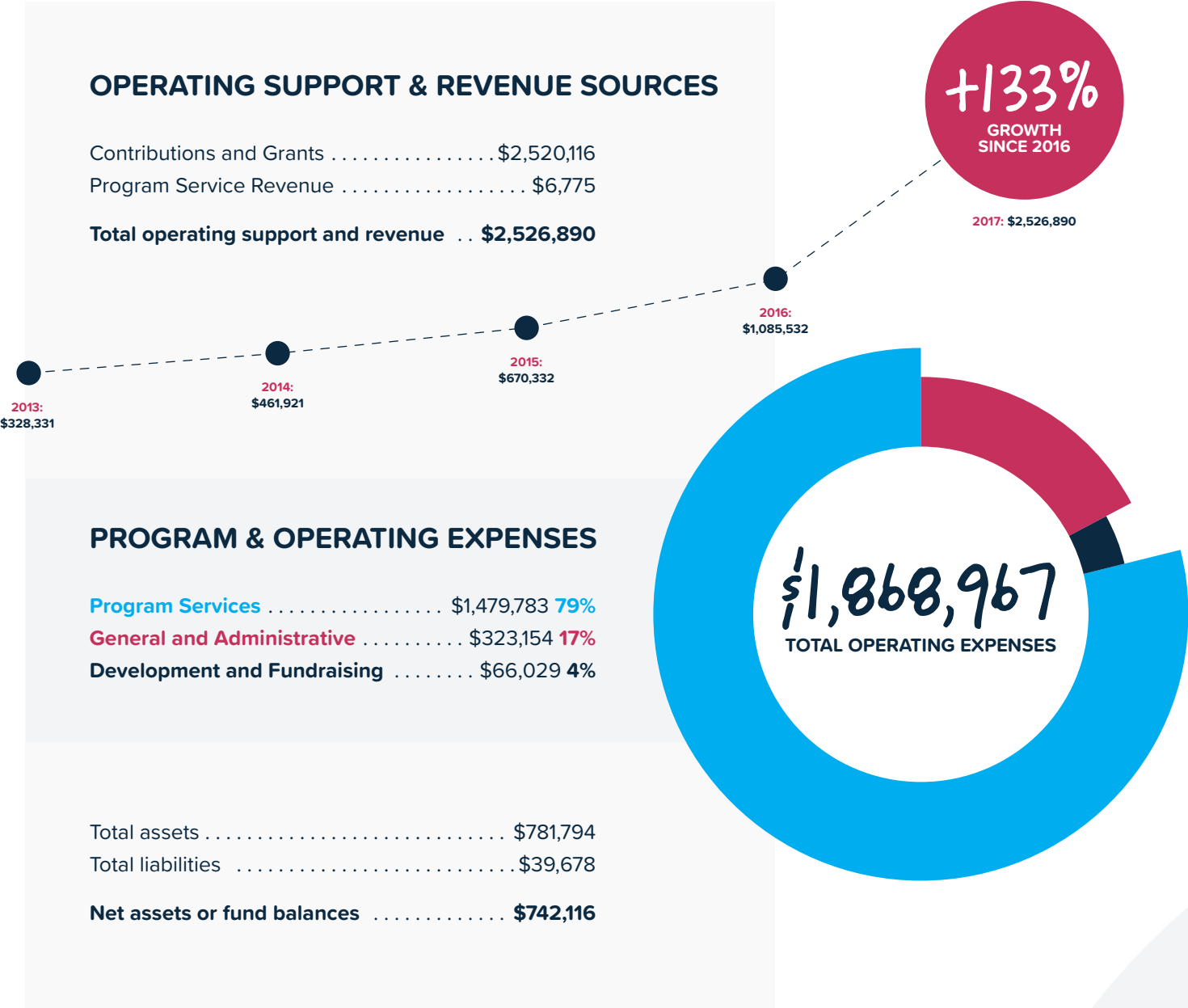
QUARTZ

America's current patent system inhibits innovation. Here's how to fix it.

"Junk patents don't belong in the American story of innovation, ingenuity, and free market..."

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.



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

For the past 12 years, Médecins Sans Frontières/Doctors Without Borders (MSF), through its Access Campaign, has supported and worked closely with I-MAK on legal strategies including opposing unmerited patents to increase people’s access to lifesaving treatments.

GLOBAL PARTNERS



“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.”

OTHOMAN MELLOUK
LEAD FOR INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES, INTERNAL 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

“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 skillfully 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

“ 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.

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|----------------|--|
| 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 |



"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

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.

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

"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](https://twitter.com/imakglobal)

Visit our website: i-mak.org