

INTEGRATING PUBLIC VOICES
INTO THE PATENT SYSTEM:

A BLUEPRINT FOR REFORMS



In a historic time of a global pandemic, a drug pricing crisis, cultural and racial transformation, and as technology rapidly changes everyday life, never before has public engagement been more important.

The United States' patent system is intended to create incentives that promote new inventions and products for the benefit of the public. To meet this historic moment and to evolve with emerging societal needs, public input must be meaningfully integrated at every level of the patent system.

THE PATENT SYSTEM AFFECTS ALL AMERICANS, SO ALL AMERICANS SHOULD HAVE THE ABILITY TO AFFECT THE PATENT SYSTEM.

This paper is a synthesis of information gathered through literature reviews, key informant interviews, and the convening of a diverse group of stakeholders to identify potential policy options for integrating public voices into the U.S. patent system. The recommendations in this paper were selected because they meaningfully engage the broader public, are acceptable to a range of stakeholders, and are operationally feasible in the current system.

PUBLIC PARTICIPATION BLUEPRINT

EXPANDING PUBLIC ENGAGEMENT AT THE PATENT AND TRADEMARK OFFICE, AND BEYOND



Redefine the “customer” to extend beyond patent holders and applicants to ensure that the broader public is a key stakeholder in the patent system.

1. **Incorporate the broader public** – those with lived experience and those who are affected by the system – into the mission of the Patent & Trademark Office (PTO).
2. **Modernize existing pathways** for public engagement by updating the membership and charter of the Patent Public Advisory Committee.
3. **Create new pathways** for public participation at the PTO by establishing an Office of the Public Advocate and a Public Engagement Advisory Committee.



Make patent policy and decision-making more participatory.

1. **Conduct listening sessions** with the broader public ahead of and during any rulemaking.
2. **Establish and formalize interagency communication** and coordination to create or expand public participation processes that are responsive to broader public needs.



Protect and expand the broader public’s ability to challenge patents.

1. **Reduce or waive the cost of challenging patents** for nonprofit and public interest organizations.
2. **Allow more robust opportunities to challenge a patent before it is issued**, to help strengthen the quality of the patents granted.
3. **Give the broader public the right to appeal** if they lose a patent challenge.

INTRODUCTION

The United States' patent system is intended to create incentives that promote new inventions and products for the benefit of the public. When the system is working well, it has the potential to improve lives through the development of new science and technology. When the system is out of balance, it can cause harm. For example, if a drug company's patenting activity is blocking a generic drug from entering the market, it can restrict drug access and keep prices high. This in turn creates a cascade of health and economic implications for American families and society at large.

There is growing acknowledgment that when the patent system is used improperly it fortifies monopolies that block competition. This can harm consumers, U.S. businesses, and the economy. Even though the daily lives of citizens and communities are affected by this system, their voices are often missing in patent policy debates. Conversations that are technical and legally complex prioritize the views of well-resourced patent owners, lobbyists, and applicants – mainly commercial interests – and there is no balance of public interest voices to raise the individual and societal implications that should be considered.

To expand public participation, a number of challenges must be addressed, including first and foremost that the broader public is not considered a key stakeholder in the patent system. To seek solutions and imagine a new paradigm where the system can be more accountable to those individuals and communities who are affected by its decisions, in 2021 I-MAK developed a process called Participatory Changemaking (PCM). This process consisted of literature reviews, key informant interviews, and a convening of diverse stakeholders including patients, scientists, investors, policymakers, patent lawyers, judges, and economists.

BASED ON THE LEARNINGS OF PCM, THIS BLUEPRINT INCLUDES:

Key principles to increase public participation (page 4)

Barriers to broader public engagement in the patent system (page 5)

Policy options based on these learnings (page 7)

IN PRACTICE, WHO IS PART OF THE PATENT SYSTEM?



KEY PRINCIPLES TO INCREASE PUBLIC PARTICIPATION

Creating opportunities to meaningfully integrate the perspectives of the broader public to help shape patent policy and decision-making means including all types of stakeholders. **The broader public includes those who have technical knowledge of the topic being discussed, those who are affected, those representing the public's interest, and those who simply have the desire to be involved.**

PUBLIC PARTICIPATION IN THE PATENT SYSTEM SHOULD BE GUIDED BY THREE PRINCIPLES:

1. Members of the broader public are key stakeholders in the patent system and have a legitimate voice in patent policymaking processes. Engagement with technical and non-technical stakeholders in an intentional, accessible, equitable process is critical.
2. Public participation processes should have clear rules and expectations of how input is sought and used, and create opportunities for iteration and feedback from idea generation through to implementation.
3. Policymakers and agencies should be committed to transparency throughout the process.

BARRIERS TO PUBLIC PARTICIPATION

The patent system has many parts, including courts and case law, legislation, international treaties and agreements, and administrative rules. Experts have noted that from its inception, the U.S. patent system “did not articulate any explicit considerations or exceptions on the basis of the public interest.” Furthermore, it “seemed to settle on the idea that the public interest would be best served if the patent system

and the market were left alone to work¹, with government playing a minimal, certifying role”. This leads to structures and decisions where the public’s interest in the patent system is overshadowed by commercial concerns and responsive only to those who have the legal and technical expertise to apply for or hold patents or administer the system.

The PCM process identified that currently, there are three main entry points for stakeholders to engage with the American patent system. Understanding these pathways and the barriers that exist within and around them is critical to identifying where and why the voice of the broader public is absent and what can be done to correct this imbalance.

EXAMPLES OF ENTRY POINTS AND BARRIERS



GO TO COURT JUDICIAL BRANCH

- File litigation
- File a supporting document to assist a court on an existing case by offering information, expertise, or insight (“Amicus Brief”)

Requires standing, or sufficient legal interest or actual harm, to participate in the case.



ENGAGE LAWMAKERS LEGISLATIVE BRANCH

- Engage Members of Congress by:
- Advocating for laws and reforms
 - Public demonstrations
 - Social media
 - Other avenues

Lack of financial resources, power, networks, proximity, reputation, or invitation to have true access to decision-makers or a seat at the policymaking table.



ENGAGE WITH THE PATENT OFFICE EXECUTIVE BRANCH

- Challenge patents at the Patent Trial and Appeal Board
- Comment on how the agency makes its rules and policies
- Attend public roundtables
- Serve on the Patent Public Advisory Committee

The broader public is not considered a “key stakeholder” akin to patent holders or applicants. Individuals and communities are often excluded because participation requires a certain amount or type of knowledge, expertise, relationships, reputation, or financial resources.

BARRIERS

The following are examples of groups that have tried to participate in the patent system to alleviate public harms and have faced institutional, financial, cultural, and or technical barriers:

- FARMERS
- WOMEN AT RISK FOR BREAST OR OVARIAN CANCER
- HIV PREVENTION ADVOCATES
- PATIENT ADVOCATES

The PCM process identified significant barriers to public engagement with courts and lawmakers, and the agency responsible for granting U.S. patents, the United States Patent and Trademark Office (PTO). The mission² of the PTO is to “foster innovation, competitiveness and economic growth.” The purpose of this mission is to benefit all citizens and society at large; however, the agency primarily serves and is responsive to those entities that apply for and hold patents. The agency sees its “customer” as patent holders and applicants. As such, efforts by non-applicants to engage at the agency level are reported to face significant barriers.

The requirement of having legal and technical expertise to be considered a key stakeholder deserving a seat at the policymaking table is pervasive. **Legitimate concerns presented without the veneer of legal and technical expertise are easily dismissed, creating a significant barrier to participation.** An illustrative example is the charter for the Patent Public Advisory Committee (PPAC), the main body intended to represent the public to the PTO, which

states that its members are “individuals with substantial background and achievements in intellectual property, finance, management, labor relations, science, technology, and office automation.”³ Missing from these definitions is a consideration of the broader public – those who have lived experience and are affected by policies and decisions at the individual, community, or organizational level – and a recognition that their inputs are legitimate and necessary.

Even when legal and technical expertise is present, however, the views of the broader public may still be excluded. Several individuals and expert organizations, including the Public Patent Foundation, Engine Advocacy, and the Electronic Frontier Foundation, reported that previous requests were made for the PPAC to include public interest representation. To date the PPAC does not include members representing the interest of the broader public. This is telling of the patent system as a whole: while today’s patent system offers pathways for some stakeholders to engage, particularly those who hold or apply for patents, there is a growing need for individuals and communities affected by patented technologies to have more opportunities to participate.

PUBLIC PARTICIPATION BLUEPRINT

Guided by the principles and solutions informed by the PCM process, we offer potential policy options to integrate public voices and deepen equity and inclusion in the patent system. The solutions presented are not exhaustive but were selected because they meaningfully engage the broader public, are acceptable to a range of stakeholders, and are operationally feasible in the current system. The recommendations presented below focus on the PTO unless otherwise noted.

THREE PATHS TO INCREASE PARTICIPATION IN THE PATENT SYSTEM:



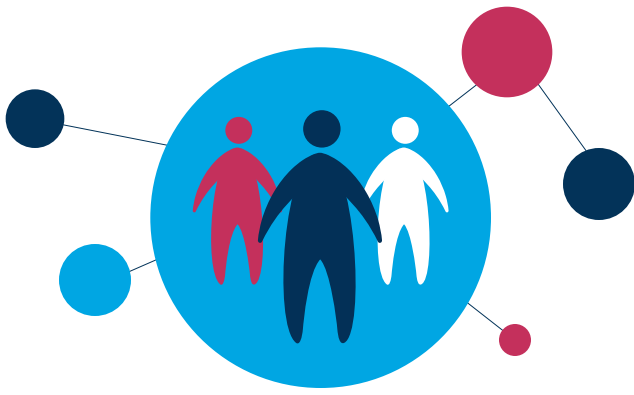
Redefine the “customer” beyond patent holders and applicants to ensure that the broader public is a key stakeholder in the patent system.



Make patent policy and decision-making more participatory.



Protect and expand the broader public’s ability to challenge weak patents.



REDEFINE THE “CUSTOMER” TO EXTEND BEYOND PATENT HOLDERS AND APPLICANTS TO ENSURE THAT THE BROADER PUBLIC IS A KEY STAKEHOLDER IN THE PATENT SYSTEM.

Reframe the definition of “customer” in the patent system to include individuals and groups representing the broader public’s interest. In both policy and practice, the PTO should redefine its key stakeholder base to include not just those who are directly applying for patents and trademarks, but also those with lived experience and those whose lives stand to be fundamentally affected by these decisions.

- 1. The Patent and Trademark Office should incorporate the broader public’s interests into its mission and definitions.** Acknowledging the patent holders’ interests alongside the interests of those affected by patents will bring a balance between the public’s interest and the power of industries. The PTO’s mission and definitions should recognize that individuals and communities who are not patent holders or applicants are key stakeholders in the system and have the same legitimacy as those who seek patents and have commercial interests.
- 2. Modernize existing pathways for public engagement by updating the membership and charter of the Patent Public Advisory Committee.** The charter of the Patent Public Advisory Committee⁴, which advises the Director of the PTO on patent and operational issues, states that the committee must “represent the interests of diverse users” of the agency. However, currently the Patent Public Advisory Committee is composed primarily of representatives with commercial interests. People with non-commercial perspectives — such as members of historically

marginalized communities, patients, and public interest advocates — who have a tremendous stake in how monopolies operate are not represented. In order to correct this imbalance, the PTO should make several changes to the committee, including: amend the charter of the committee so that it has more influence over how the agency operates and implements policy; add members of the broader public so that they have the same standing and authority as corporations and lawyers on the committee; provide stipends to the members representing the broader public; and require that each meeting have at least one agenda item included from the members representing the broader public.

- 3. Create new pathways for broader public participation at the PTO by establishing an Office of the Public Advocate and a Public Engagement Advisory Committee.** The Office of the Public Advocate would be located within the Patent and Trademark Office and would be charged with engaging individuals and groups representing the public’s interest. In addition to serving as an entry point into the agency, the office would create consumer-facing resources and educational materials to support non-technical stakeholders in their participation with the patent system. The new Public Engagement Advisory Committee would advise the Director of the PTO on issues relating to public participation and how to integrate the broader public in the work of the agency. Membership would comprise a diverse group of stakeholders, including those with lived experiences and a desire to be involved in the patent system, public participation, and deliberative democracy practitioners, and transparency experts. The committee would inform the agency’s processes and activities to build transparency in the patent system; integrate non-technical stakeholders in an intentional, accessible, and equitable approach; and provide feedback on how the agency is doing in terms of integrating the broader public.



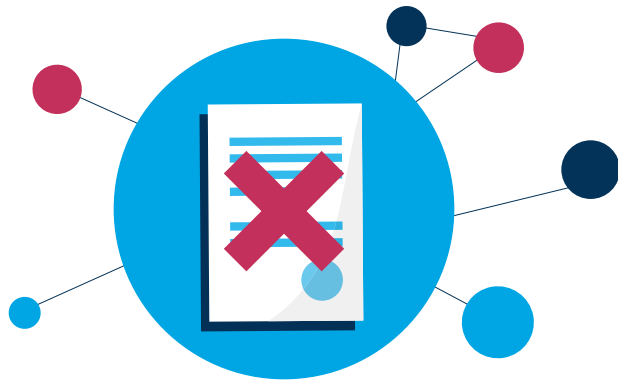
MAKE PATENT POLICY AND DECISION-MAKING PROCESSES MORE PARTICIPATORY.

Proactively engage the broader public fully in policy and decision-making processes to raise awareness of issues, share knowledge, inform decisions, build agreement, and implement equitable policies. Beyond engagement and acknowledgment, there is an opportunity for the PTO to integrate the broader public's interest fully in the policymaking process. Generating and cultivating participation in policy and decision-making processes means that the broader public must be engaged in a meaningful way with a realistic understanding of how input will be used to inform policy.

1. Conduct "listening sessions" with the broader public ahead of and during any rulemaking. Every rule or policy the PTO considers changing has a ripple effect through the U.S. economy, and therefore the entire public. While in many cases proposed rule changes are published in the Federal Register and are open to public comments, knowing when and where to look and how to respond to this bureaucratic and technical process can feel like insider baseball to a general citizen. Prior to and throughout any rulemaking or significant policy change, the PTO should proactively convene listening sessions among the individuals and communities who stand to be affected by these changes and create opportunities to speak with and learn from the public before and during the rulemaking process. Those who routinely use the system to seek and hold patents and those who are familiar with federal rulemaking processes – like well-resourced commercial actors and lobbyists – meet regularly with federal agency representatives to submit information and perspectives to the PTO. Ensuring the same level of access to

all key stakeholders, including the broader public, would allow the agency to gather information and knowledge reflecting the insights and diverse perspectives from the individuals who will be affected.

2. Establish and formalize interagency communication and coordination to create or expand public participation processes that are responsive to broader public needs. Understanding how patents affect individuals and communities across many systems and how those with lived experience can be integrated into decision-making processes requires a comprehensive, multidisciplinary effort. Numerous federal departments and agencies are currently evolving their public participation processes to be more inclusive, and the time is ripe for the PTO to join them. The Federal Trade Commission recently made the agency's monthly meetings open to the public⁵ and added more opportunities for public input and accountability⁶ in the Commission's response to rulemaking petitions, and the United States Trade Representative announced a set of transparency principles⁷ that confirm a new commitment to public engagement⁸, including outreach to historically overlooked and underrepresented communities. In addition, other agencies and departments have well-developed and long-standing models to consult and collaborate with the individuals and communities who are affected by their policies and decisions. For example, the Center for Medicare Services has a person and family strategy⁹ to engage patients across the country, and the Environmental Protection Agency¹⁰ holds public meetings on proposed projects and policies, as well as regional roundtables to allow stakeholders with a range of perspectives to discuss their experiences. Interagency collaboration will provide opportunities for the PTO and other members to develop new pathways for public participation.



PROTECT AND EXPAND THE BROADER PUBLIC'S ABILITY TO CHALLENGE PATENTS.

Ensure individuals and groups representing the public can challenge patents that restrict progress and access to technologies. Every decision the PTO makes to issue a patent implicates the public, because that patent gives one company the right to exclude everyone else in the country from making, using, or selling what that patent claims. And if the PTO gets things wrong (which it at least occasionally does), and grants a patent incorrectly, that can cause substantial harm. In court, parties routinely challenge invalid patents, but that is extremely expensive and basically requires one company to be sued first, leaving few avenues for the public to participate. But in 2011, Congress created new procedures for any person—including the broader public—to go back to the PTO and file a challenge, essentially asking the PTO to take a second look at a weak patent through an entity known as the Patent Trial and Appeal Board (PTAB). While these patent review tools are important, there are problems with the system that restrict public access and need to be fixed.

1. Reduce the cost of patent challenges. Filing fees to challenge patents cost upward of \$41,500 per patent and this is prohibitively expensive for individuals and groups representing affected communities. In a system heavily weighted in favor of commercial actors, legally challenging harmful patent monopolies that may have been incorrectly granted is one of the only avenues for creating equity in the market.¹¹ The financial cost of filing patent challenges in Europe¹² and elsewhere are significantly lower, and the PTO should bring its practices in line with other patent

offices worldwide to reduce these costs. One way to lower fees would be to tier the cost of a challenge depending on who files it, similar to the current small business discounted fees¹³ for patent applications (which are 50 to 75 percent less). Policymakers should not just reduce the patent review fees for small businesses but extend those same discounts to nonprofit and public interest organizations. Alternatively, fees associated with challenges filed by nonprofit or public interest organizations could be waived altogether.

- 2. Allow more robust opportunities to challenge a patent before it is issued.** Updating the law to expand the public's ability to challenge a patent prior to its grant would strengthen the patent system and provide an important new avenue for public participation. Allowing the public to challenge patents in an *inter partes* manner prior to examination would improve the quality of the patents ultimately granted, provide further examination resources to support examiners, and provide an additional legal channel for the public to participate without having to meet the current legal standing requirements in court. This policy shift would also remove the burden of the presumption of validity that a patent grant confers, which unfairly favors patent holders. Rejecting poor quality patent applications prior to their grant would help reduce litigation and other strategies that manipulate the patent system while creating more certainty for all parties.
- 3. Give the broader public the right to appeal if they lose a patent challenge.** If a member of the public files and loses a challenge to a patent at the PTAB, they currently do not have the ability to appeal that decision to court. Congress should acknowledge and define through statute the imminent harm that members of the public can face due to invalid patents. Courts should accept such acknowledgment as evidence that petitioners who are acting in the public interest have the right to appeal to the Federal Circuit in the event they receive a negative decision from the PTAB. Currently, the right to appeal a decision of the PTAB favors patent owners or those petitioners who can show a risk of suit for infringing the patent(s) in question. The ability to appeal an unfavorable PTAB decision should be made more accessible to stakeholders who have no patent or commercial interest at stake but are affected by such decisions in terms of the harm caused to them on an individual basis.

ABOUT PARTICIPATORY CHANGEMAKING

This paper leveraged I-MAK's "Participatory Changemaking" (PCM) process, a multidimensional assessment of the patent system informed by real world insights and input from the public perspective. PCM brings together individuals from different geographic, political, personal, and professional backgrounds to generate new ideas of how to modernize the patent system. Interaction among stakeholder groups who hold different views about the role of patents in society is extremely limited, and a participatory process builds much needed connection and understanding between diverse participants. This multi-stakeholder approach delivers a policy blueprint that is implementable and inclusive of the public's interest, and that can create meaningful change.

This blueprint is a synthesis of literature review, interviews, and group dialogue with individuals and organizations representing stakeholders who hold or apply for patents, administer the system, and are affected:

- Patent lawyers
- Government agencies
- Patent judges
- Patent holders
- Small and medium enterprises
- Senior citizens
- Patients
- Consumers
- Public participation advocates
- Affected communities
- HIV prevention advocates
- Academics
- Media
- Economists
- Think tanks
- Policymakers
- Investors

ABOUT I-MAK

The Initiative for Medicines, Access, and Knowledge (or I-MAK) is a 501(c)(3) organization with a mission to build a more just and equitable medicines system. Our framework integrates deep analytical research, stakeholder informed collaboration, and a voice in the media to activate change through education. We bring decades of private-sector expertise and an evidence-based approach to this mission, spanning 50 countries and including engagement with patients, drug manufacturers, patent offices, community leaders, public health professionals, policymakers, scientists, economists, and more. I-MAK's work on structural change in the patent system is featured regularly in the national and global press, as well as Congressional hearings and Committee reports. In early 2021, I-MAK proposed a 10 point plan¹⁴ to increase equity and competition through the patent system to help inform policy solutions going forward.

LEARN MORE ABOUT I-MAK'S WORK AT

<https://www.i-mak.org/>



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