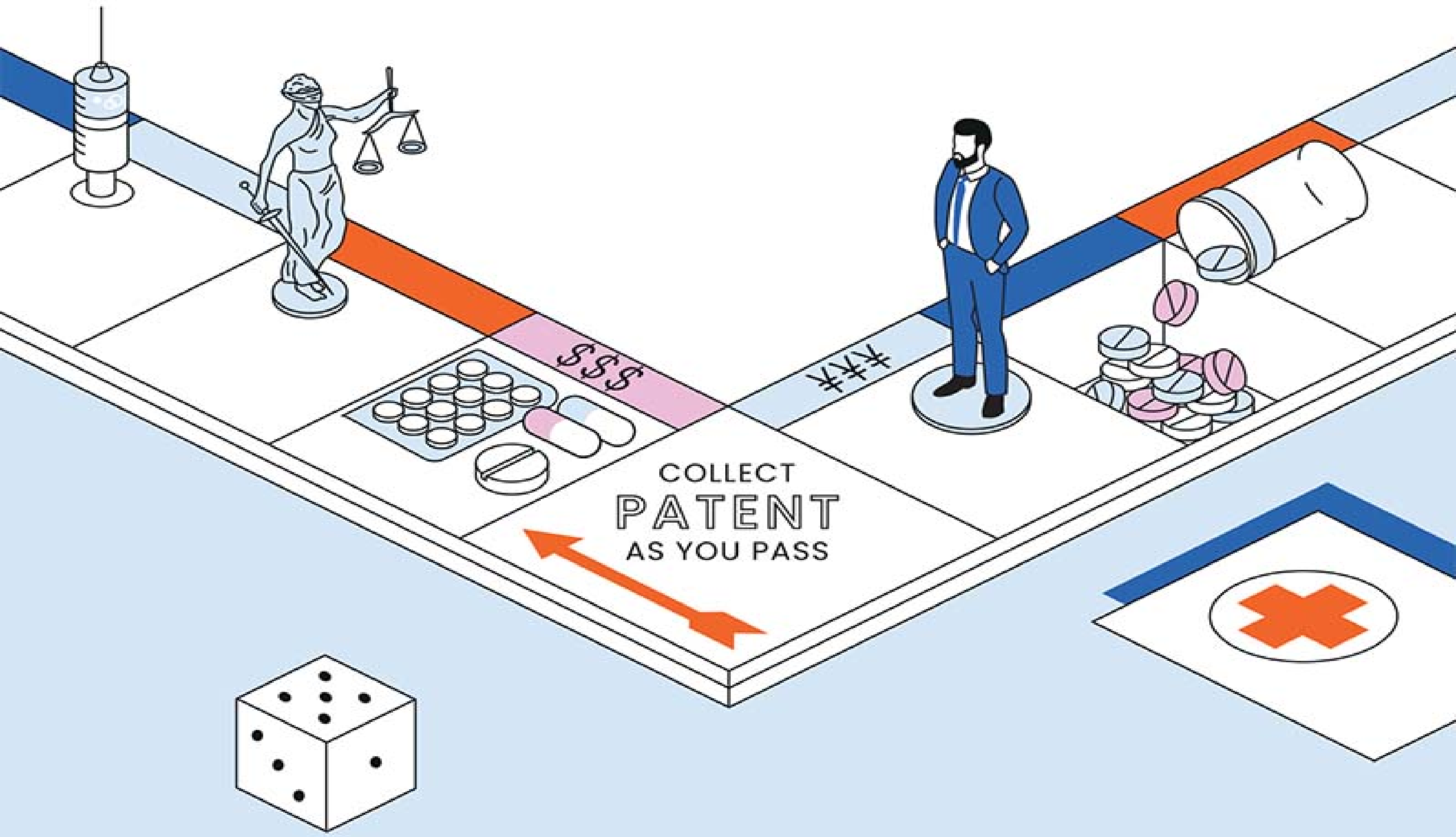
PHARMA MONOPOLY

The Battle for the Future of Medicines



TAHIR AMIN & ROHIT MALPANI

CONTENTS

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Tahir Amin & Rohit Malpani

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Abbreviations and Acronyms

ACTA
Anti-Counterfeiting Trade Agreement

ACT-A
Access to COVID-19 Tools Accelerator

ACTPN
Advisory Committee on Trade and Policy Negotiations (United States)

ACT UP
AIDS Coalition to Unleash Power

AGI
artificial general intelligence

AI
artificial intelligence

AIDAN
All India Drug Action Network

AMC
advanced market commitment

ARV
antiretroviral

BMS
Bristol Myers Squibb

BRICS
Brazil, Russia, India, China, South Africa

CAFC
Court of Appeals for the Federal Circuit (United States)

CAS
Chinese Academy of Sciences

Centad

Centre for Trade and Development

CEPI

Coalition for Epidemic Preparedness Innovations

CGD

Center for Global Development

CHAI

The Clinton Health Access Initiative

COVAX

COVID-19 Vaccines Global Access

CSO

civil society organization

C-TAP

COVID-19 Technology Access Pool

DLC

Democratic Leadership Council

DNDi

Drugs for Neglected Diseases Initiative

DNP+

Delhi Network of Positive People

DOGE

Department of Government Efficiency (United States)

EMR

exclusive marketing right

EU

European Union

EVD

Ebola virus disease

FDA

Food and Drug Administration (United States)

G6

Group of 6

G7
Group of 7

G8
Group of 8

G77
Group of 77

GATT
General Agreement on Trade and Tariffs

Gavi
Global Alliance for Vaccines and Immunizations

GLP-1
glucagon-like peptide-1

GSK
GlaxoSmithKline

IFPMA
International Federation of Pharmaceutical Manufacturers and Associations

IGO
intergovernmental organization

IHES
Initiative for Health, Equity, and Society

I-MAK
Initiative for Medicines, Access & Knowledge

IMF
International Monetary Fund

INP+
Indian Network of People Living With HIV/AIDS

INTs
individualized neoantigen therapies

IP
intellectual property

IPC

Intellectual Property Committee

IPO
Indian Patent Office

ITO
International Trade Organization

ITPC
International Treatment Preparedness Coalition

J&J
Johnson & Johnson

LOCOST
Low-Cost Standard Therapeutics

LSF
Liberté sans Frontières

MIT
Massachusetts Institute of Technology

MPP
Medicines Patent Pool

MRI
magnetic resonance imaging

MSF
Médecins sans Frontières

NAM
Non-Aligned Movement

NGO
non-governmental organization

NHS
National Health Service (United Kingdom)

NIEO
New International Economic Order

NWGPL
National Working Group on Patent Laws (India)

OECD
Organization for Economic Cooperation and Development

OPEC
Organization of the Petroleum Exporting Countries

PATH
Program for Appropriate Technology in Health

PDP
product development partnership

PEPFAR
President’s Emergency Plan for AIDS Relief (United States)

PET
positron emission tomography

PhRMA
Pharmaceutical Research and Manufacturers of America

PPP
public–private partnership

R&D
research and development

TDF
tenofovir disoproxil fumarate

TPP
Trans-Pacific Partnership

TRIPS
Trade-Related Aspects of Intellectual Property

UN
United Nations

UNAIDS
Joint United Nations Programme on HIV/AIDS

UNCTAD
United Nations Conference on Trade and Development

UNDP
: United Nations Development Programme

UNICEF
: United Nations Children’s Fund

USAID
: United States Agency for International Development

USTR
: United States Trade Representative

WHO
: World Health Organization

WIPO
: World Intellectual Property Organization

WTO
: World Trade Organization

ONE
The Illusion of Access

> *We know that no one ever seizes power with the intention of relinquishing it. Power is not a means; it is an end.*
>
> George Orwell, *1984*[1]

The UK Prime Minister, Boris Johnson, was livid. He fumed that his country had a right “to take that which was legally ours and which the UK desperately needed.” Johnson was referring to a 2021 plan to carry out an “aquatic raid” to grab 5 million AstraZeneca Covid vaccines sitting at the Dutch Halix plant.[2] This tug of war over vaccines between the United Kingdom and the European Union (EU) provided a snapshot of what wealthy Western nations were willing to do to stockpile as many doses as possible during Covid. It was also in sharp contrast to what wealthy Western nations were *not* willing to do. While Johnson was plotting military operations to access vaccines, the UK government, the EU, and other wealthy nations were *not* agreeing to permit countries in the Global South[3] to manufacture Covid vaccines and drugs for themselves.[4]

Their objection was against waiving the global intellectual property (IP) rules that the World Trade Organization (WTO) had established under the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) in 1994. Were a waiver to be allowed, the few Western pharmaceutical companies that were holding the recipes and rights to manufacturing the vaccines and drugs would no longer have a monopoly. With the limited global supply of vaccines gobbled up by wealthy nations, it was predicted (correctly) that many people in the Global South would not see their first vaccine shot until 2023. The actions of the UK government and other wealthy nations would suggest it was more important to them to protect IP rights and an economic rules-based order which had been designed to maintain the immense power they shared with the pharmaceutical industry.

Looking back, the pandemic years from 2020 to 2022 now feel like a blur. The endless Zoom calls, lockdowns, constant news of illness and death, and an unabating effort to change the course of the biggest public health crisis in over 100 years can do that. The impact of Covid-19 is still being digested by many on a personal level. For those of us who work in the arena of public health and what is known as the "access to medicines movement," it continues to occupy our attention. In the aftermath, we now know that the estimated death toll associated directly or indirectly with Covid-19 was nearly 15 million people in the first two years of the pandemic. The majority of these deaths were in middle- and lower-middle-income countries.[5]

The World Health Organization (WHO) would officially announce the end of the Covid pandemic in May 2023. It is estimated that at the time some 2.2 billion people had still not received a single vaccine shot against the disease. Shockingly, 89% of those people lived in lower-middle-income and low-income countries.[6] These were countries that were systematically pushed to the back of the queue by Western pharmaceutical companies and wealthy nations who had hoarded enough vaccines to inoculate their populations several times over. Not satisfied, they would jump the queue again to grab booster shots. Despite the repeated narratives from Western governments and pharmaceutical companies of issues in the Global South such as vaccine hesitancy, inadequate public health systems, logistical delivery challenges, lack of facilities to cold-store vaccines, or waning demand, there was enough evidence to suggest these claims were exaggerated. In fact, the major limiting factor was the inequitable supply of vaccines.[7] But it was too late by then. Those in power who had secured access or billions in profits were returning to normalcy. The rich countries had decided the pandemic was over and it was time to move on. The pharmaceutical companies saw an opportunity to increase their prices for vaccines now that Covid was classified as endemic.

Despite all the experience of global health agencies fighting epidemics and pandemics, the largest coordinated civil society advocacy effort in years, and the constant media scrutiny exposing the misleading narratives of the Global North and its pharmaceutical industry, everything played out according to the logic of the existing economic rules-based order. Often such understanding only comes with hindsight, but the predictable outcomes were happening in front of us in real time. When challenged with humanity's collective cry to waive IP rights, pharmaceutical companies, Western governments, and the billionaire philanthropist Bill Gates called such demands "nonsense."

In other words, might was right. The Global North and its pharmaceutical companies had the power to determine the outcome so that it suited their economic paradigm, yet claimed it was still in the best interests of everyone. Parroting the pharmaceutical industry's talking points, Western government leaders would shift the goalposts when contradicting facts and evidence undermined their arguments. In one instance, they would argue the scarce vaccine supply was because of a lack of raw materials. Then it was because all the companies and plants capable of manufacturing vaccines were at full capacity. There were also the usual tropes. The *Wall Street Journal* Editorial Board would write that "even if intellectual property rules were waived and technology was shared, manufacturers in the Global South did not appear to have the ability to make such complex technologies, let alone distribute them."[8] Bill Gates and his Foundation, who have developed untold power and persuasion in public health circles, a topic we discuss in Chapter 4, said it would be unhelpful for IP protections to be lifted. For Gates, sharing the recipes for making the vaccine with manufacturers in the Global South to scale up supply was not feasible: "It is only because of our grants and expertise that can happen at all," Gates said, referring to moving vaccine manufacturing to India.[9]

After much criticism from governments in the Global South and public health advocates, there was eventually a reluctant acknowledgment that IP rights were getting in the way. The most prominent shifts would come from the Gates Foundation's CEO, Mark Suzman, reversing the organization's opposition[10] and the United States Trade Representative (USTR) symbolically supporting a waiver of patents for medical technologies.[11] Many others, in particular the European Commission, Germany, and the United Kingdom, continued to put up obstacles by deflecting, distracting, and buying time until the pandemic ended. Reliving these events and recalling the statement of European Commission President Ursula von der Leyen at the beginning of the pandemic that "the vaccine will be our universal common good"[12] leaves the bitter realization that we were being gaslighted all along.

The arguments of the pharmaceutical industry and Western governments against waiving IP rights were also given cover by prominent liberal think tanks in the international development sphere. One that defended the status quo was the Center for Global Development (CGD), an organization whose prominent role in shaping financial mechanisms for purchasing vaccines we discuss in Chapter 4. The CGD is a Washington, DC-based global public health think tank whose claimed mission is to reduce global poverty with evidence-informed policies. It boasts the influential neoliberal economist Larry Summers as its Board Chair. At the height of the pandemic, I (Tahir) featured on the *New York Times* podcast *The Argument*, along with a CGD global health fellow named Rachel Silverman. When pushed by the podcast host on the problems of the current system and trying something new to address the inequitable distribution of vaccines, Silverman responded: “But my concern is, we’re in a mass casualty event right now. And to me, we need to get ourselves out of that as quickly as possible. And then I’m very happy to do a postmortem on everything that went wrong and potentially be more radical in thinking.”[13]

This pragmatic response typified those of Western governments, the pharmaceutical industry, and anyone else who was against removing the obstacles of the IP rules-based order. The Global North and its pharmaceutical companies were content with making token vaccine donations, some of which had gone past their expiry date. Translated, it was just another empty gesture and cruel way of waiting things out until the world had moved on so business as usual could resume. In our experience in this field, there are rarely postmortems that involve a radical rethink. Mostly, there is a lot of historical revisionism by those who have committed acts of injustice.

Instead of taking radical action while millions were dying, Western governments and the pharmaceutical industry jumped on the “equity” bandwagon to show they cared. Alongside ill-timed donations, Pfizer would run a full-page advertisement in *The New York Times* claiming equity was their “north star.”[14] In reality, this was all just lip-service. The only equity that ultimately mattered was their shareholders’ and their powerful government benefactors’.

And no one knows how to get close to power better than the pharmaceutical industry.

Between 2021 and the second quarter of 2024, more than 500 lobbyists were hired to oppose the waiving of IP under the TRIPS Agreement.[15] This lobbying also targeted ongoing pandemic preparedness negotiations around IP. Pharmaceutical and biotechnology companies, or industry groups with pharmaceutical or biotechnology company-affiliated members, hired the highest number of lobbyists. The Pharmaceutical Research and Manufacturers of America (PhRMA), which lobbies on behalf of the largest pharmaceutical companies based in the United States, spent millions of dollars hiring the second largest number of lobbyists to oppose the waiver. Pfizer, one of the most powerful pharmaceutical companies and a central actor readers will encounter in this book, was close behind.

While industry lobbyists were ensuring the US government would not give way to a full IP waiver, their European counterparts were taking aim at the European Commission. The European Federation of Pharmaceutical Industries and Associations, which represents the pharmaceutical industry in Europe, met 46 times with the European Commission between January 2020 and September 2022. In that same period, pharmaceutical lobby groups and companies met more than 360 times with UK officials, with Boris Johnson personally attending 11 of them.[16]

Although the Covid pandemic was a seismic event, this book is not just about that. But it is the reason why we wanted to write it. By the end of the pandemic, we had each spent two decades working in the access to medicines movement. This movement emerged in response to the HIV/AIDS pandemic in the late 1990s. Global public health advocates, local and transnational non-governmental organizations (NGOs) such as Médecins sans Frontières

(MSF), and HIV/AIDS activists joined forces when antiretroviral (ARV) medicines were inaccessible to many in South Africa and elsewhere in the Global South. These life-saving medicines were priced far beyond what most people could afford. The ethos of the movement was based as much on justice, human rights, and challenging structural power systems, such as the WTO, as it was on making medicines accessible and affordable to all.

One of those systems of power was and still is IP. Under the WTO TRIPS Agreement that was created with their governments, branded pharmaceutical companies from the Global North wielded against the Global South a recently globalized intangible private property over knowledge. This privatization of knowledge had previously operated under the distinct law of patents. With the rise of neoliberalism and property rights economics in the 1970s, the privatization of knowledge came to be housed under the new concept of IP. IP would now cover the distinct laws of copyright, trademarks, designs, and any other intangible property right that business could concoct and monetize.

Patents, which today typically provide a 20-year monopoly right for an invention, were just one of the types of IP rights that pharmaceutical companies used to block affordable versions of medicines, commonly known as generics. They would also be a key policy tool to stymie competition emerging from the Global South. Over the last two decades, we have worked on addressing patent and other IP barriers to pave the way for affordable access to medicines. In tandem, we have challenged the underlying power and control exercised by the pharmaceutical industry and their governments. This includes seeking to overcome the lack of research and development (R&D) for diseases that predominantly affect people in the Global South, because patents usually encourage drug companies to only develop medicines for diseases that affect the world's wealthy countries. It is a trend that may get even worse in the decades to come with the onrush of artificial intelligence (AI) and the personalization of medicines.

Whether it be medicines for treating cancer, hepatitis C, HIV/AIDS, malaria, rheumatoid arthritis, tuberculosis, or vaccines for human papillomavirus, Ebola, pneumonia, and Covid, we have witnessed various IP challenges, their impact, and the solutions proposed to address the inequities of the system. As the Covid pandemic unfolded, in between the endless advocacy, media interviews, and writing of opinion pieces, we would have weekly calls to each other to vent about the inadequacy of the various strategies adopted to prevent vaccine apartheid. The question that kept coming up was why, even in a global pandemic and faced with the ongoing specter of millions of deaths, the solutions being put forward and adopted lacked any long-term strategy to address the structural power imbalances. Instead, they served to preserve the status quo. Other than the effort to introduce a global waiver of IP rules under the WTO TRIPS Agreement, where was the radical rethink of the current hierarchy of power and privilege that masquerades as the rules of the road?

Our conversations have continued, and the more we have discussed, the more we have reflected on how we have got where we are. The more we have reflected, the more we have dug into how the access to medicines movement and the wider global health machinery were constructed and have evolved over the past 20 years. How have the interventions of the movement impacted the ability to ensure affordable access to medicines? Have governments, intergovernmental organizations (IGOs), global public health institutions, and philanthropy aided or hindered the process? Are they in the service of changing the structural power of the Global North and the unjust business practices of the pharmaceutical industry? Is the goal now solely focused on gaining charitable access to medicines in the fastest manner possible, even if it means cementing the current power-based order? More importantly, are these objectives in tension with each other, or can both approaches coexist and complement one another? The fundamental question is: what comes next, and are governments and civil society ready? In considering these questions, we have looked back into history and our own experience in the field to understand how the underlying ideology and philosophy that drive the outcomes and solutions on offer have taken hold.

The World Is Not Flat

Coming of age in the 1990s, as we both did, was to enter a brave new world. The global map and world order were changing in many ways. The dissolution of the Soviet Union; the re-unification of Germany after the fall of the Berlin Wall; the break-up of Yugoslavia; the creation of the EU; and the end of apartheid in South Africa: these were just a few of the events that would shape this period and beyond. We had reached the end of history, as the American political scientist Francis Fukuyama would claim. Market capitalism and democracy had defeated conservative authoritarianism and socialist planning. We had arrived at the end point of humankind's ideological evolution and the universalization of Western liberal democracy as the final form of human government.[17] This meant that Western-backed democracy and capitalism would dictate how a world at the end of history would be governed.

This decade also heralded the arrival of a new era driven by technology. There was the emergence of the World Wide Web and the internet; email; mobile phones that were not the size of a brick; and compact discs replacing cassette tapes, which would give way to compressed music on MP3 players, and then the first iPod. Consumer technologies were evolving at a pace never seen before. This meant that the planned obsolescence of products was accepted by the public and integral to how businesses could steadily increase revenues and profits. With an economy increasingly driven by the dictates of the financial sector and markets, now termed financialization, this was a cocktail made in heaven for corporations, investors, and shareholders. It would be this cocktail that would also help fuel the Second Gilded Age, where new monopolies and the worship of a modern breed of billionaire robber barons would take hold.

But instead of calling it what it was, the word “innovation” would enter our cultural lexicon by the end of the 1990s as a concept that could mask negative externalities while evoking positivity and progress. Innovation was now the primary driver and indicator for solving our biggest challenges. We were told that technology and its homogenizing power were a force for good that would build a more level playing field and connect us. Whether it was our communication, entertainment, or our health, we were promised that everything would be cheaper and more widely available. Knowingly or unknowingly at that time, the rapid turnover of technology and constant updating of the same products for higher prices touted as “innovation” came at a price of lasting environmental and social damage. A continuous need to feed the cycle of consumption and economic growth has burdened the planet and economy with increased debt, emissions, and waste.

The 1990s also marked what many hoped to be the end of Reaganomics and Thatcherism, which had decimated many working-class communities in the United Kingdom and United States while inspiring a culture of “greed is good” and the “yuppy” class. Both Republican US President Ronald Reagan and Conservative UK Prime Minister

Margaret Thatcher had spent their years in power cementing the political economic practices and values of neoliberalism. The term “neoliberalism” is believed to have been coined at a meeting in Paris in 1938. Its prominent architects were the Austrian economists Ludwig von Mises and Friedrich Hayek, as well as members of what is known as the Geneva School of neoliberals. Over the years, neoliberalism has had the uncanny ability to morph so as to maintain its stranglehold, making it difficult to tether the concept. In essence, it is a political economic ideology and social system that supports reductions in government spending, privatization of industries, and deregulation to stimulate consumption and economic growth. Neoliberalism believes human well-being is best advanced by liberating individual entrepreneurial freedoms within a framework of private property rights, free market capitalism, and free trade. The role of the state is to guarantee the legal structures that secure investment, private property rights, and the creation or functioning of markets. Beyond that, the state’s interference in the markets should be kept to a minimum.[18]

Central to neoliberalism is the concept of individual freedom and merit-based human competition, which enforces an individualistentrepreneurial understanding of the self. Put another way, neoliberalism declares that if you cannot afford your medicines, it is your own fault, and demands you pull yourself up by your bootstraps. It does not matter if your medicine costs 10 times your salary, or that because of years of structural racism and colonialism you do not have employment or were born into poverty. It is irrelevant if the elite, powerful, and wealthy who are making these rules already have a head start in this merit-based race or are simply writing rules to enrich themselves to the detriment of others. You are solely responsible for what you deserve and deserve what you get, a form of social Darwinism. Thatcher perhaps best captured neoliberalism as an ideology and system that permeates individual values and belief when she said, “Economics are the method; the object is to change the heart and soul.”[19]

As we discuss in Chapters 2 and 5, it was the Democratic President Jimmy Carter who would first open the door to neoliberal economic policies using the language of industrial innovation. The industrial part would soon disappear, giving way to the rise of innovation and the world of finance as the drivers of economic policy. Neoliberal economic policies would both encourage globalization and shape the global political economy for the next 40 years. These policies would play a significant role in reshaping and expanding the reach of the patent system in the United States and internationally. Carter took the first step to ensure America’s hegemonic economic empire in the face of stagflation (a combination of high inflation, stagnant economic growth, and rising unemployment) and decolonization by many countries in the Global South who were increasingly demanding a more just world economy. But it was under Reagan and Thatcher in the 1980s that neoliberalism truly took hold. During their terms in office, we saw increased deregulation and privatization, the emergence of the concept of IP, huge tax cuts for the rich and corporations, the crushing of unions, and the cutting of public services, which today has been rebranded as austerity.

It was also during that decade that neoliberalism would abandon Hayek’s concerns about government-granted monopolies impeding competition and the free market. Hayek believed patents, copyright, and other forms of intangible property rights should be constrained because they stifled competition. Yet as the era of technology and informationage capitalism took hold, this new language of IP would become pivotal for multinational corporations and the Global North in shaping and controlling global trade. The missing piece at that point was the creation of a trading system governed by a supranational organization that would permanently supersede national sovereign rights. Such a system would not only preserve the intangible property rights and capital of global corporations; it would also maintain the West's economic comparative advantage and power.

What Reagan and Thatcher had cemented as a values system, Democratic US President Bill Clinton and Labour UK Prime Minister Tony Blair would continue through the next decade and into the new century through other means, as we discuss in more detail in Chapter 3. It would be Clinton who would complete what had started under Reagan: the creation of a supranational organization in the form of the WTO and the new global rules of IP under the TRIPS Agreement. These would establish what the founder of Getty Images, Mark Getty, described as the new oil of the 21st century. He was talking about IP and the rise of intangible assets as the lifeblood of the economy. "All today's richest men have made their money out of intellectual property," he said, comparing them to the wealthiest men of the past who had achieved that status through extracting natural resources.[20] Whether it be the extraction of knowledge, ideas, data, images, words, symbols, or even smells, it was all now up for private ownership globally under the TRIPS Agreement.

At the time, with Clinton and Blair now replacing the conservatism of Reaganism and Thatcherism with liberal tones, there was some optimism that the future was going to be fairer and more humane. It was during this period that we had both started our journeys as young lawyers, joining leading law firms in, respectively, the United Kingdom and the United States. Even though we did not know each other at the time, we had both pursued a legal career in what was fast becoming a “sexy” area of law, the field of IP: Tahir in the City of London and Rohit in the heart of Silicon Valley. So new was this specialized area of law in the 1990s, even lawyers from other departments in Tahir’s firm were not very familiar with what it entailed. Most lawyers were aware of the laws of land property, patents, copyright, or trademarks, but IP? Within just a decade, however, IP was everywhere, and the WTO TRIPS Agreement had a big hand in shifting culture around the concept.

For a short period before switching to a career in human rights and global health, Rohit worked alongside other lawyers on behalf of small technology companies that would turn into some of the world’s largest and most powerful firms. In that era of Silicon Valley, IP was something used to help sign deals between start-up companies that would allow them to cash in on the early internet economy. It was also a nuisance to be overcome to conduct business. Tahir, who would spend 10 years in the commercial world of IP, represented many large corporations for whom the WTO TRIPS Agreement was a godsend. It harmonized a panoply of distinct laws living under the umbrella of IP. Countries that did not previously provide protections for certain types of IP were suddenly strong-armed into drafting and enforcing laws. As lawyers, we could now instruct legal associates in those countries to protect our clients’ IP rights. For corporations and IP lawyers everywhere, it was a boon.

In contrast, for those in the anti-globalization movement, which was at the periphery of our professional lives, the new global economy had little to do with creating a global village. It was more about global pillage.[21] They rightly pointed out that it was less about trade and more about shifting capital free of national borders or laws. Globalization and global trade were a way for neoliberals to

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Z