PATENTS IN PHARMA

A Game Changer

How intellectual property shapes innovation, access, and the future of medicine

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What is a Patent?

A government-granted exclusive right preventing others from making, using, or selling an invention for **20 years** from filing date.

Novel

Entirely new — not previously known, disclosed, or patented anywhere in the world

Non-Obvious

Not an obvious extension of existing knowledge to a person of ordinary skill

Useful

Has specific, substantial, and credible utility — demonstrably works

The Staggering Cost of Drug Discovery

Patents exist because drug development demands extraordinary capital commitments with no guarantee of return.

₹130B

Cost Per Approved Drug

Average cost to bring a single drug to market (Tufts Center)

90%

Clinical Failure Rate

Drug candidates entering trials never reach approval

2/10

Recoup R&D Costs

Only 2 out of 10 approved drugs recover full investment

₹5T+

Annual Global R&D

Pharmaceutical industry investment per year

Types of Pharmaceutical Patents

Drug companies build layered IP portfolios — each patent type protects a distinct dimension of a medicine's development and commercial life.

Compound/Molecule

Protects chemical structure of active ingredient — strongest and most valuable

Process

Protects manufacturing method or synthesis route

Dosage Regimen

Protects specific dosing schedule, extending commercial exclusivity

Formulation

Covers dosage form, delivery system, or specific combination of excipients

Method of Use

Covers specific therapeutic indication or patient population

Polymorph/Salt

Covers new crystalline form offering improved stability or bioavailability

Pharmaceutical Patent Lifecycle

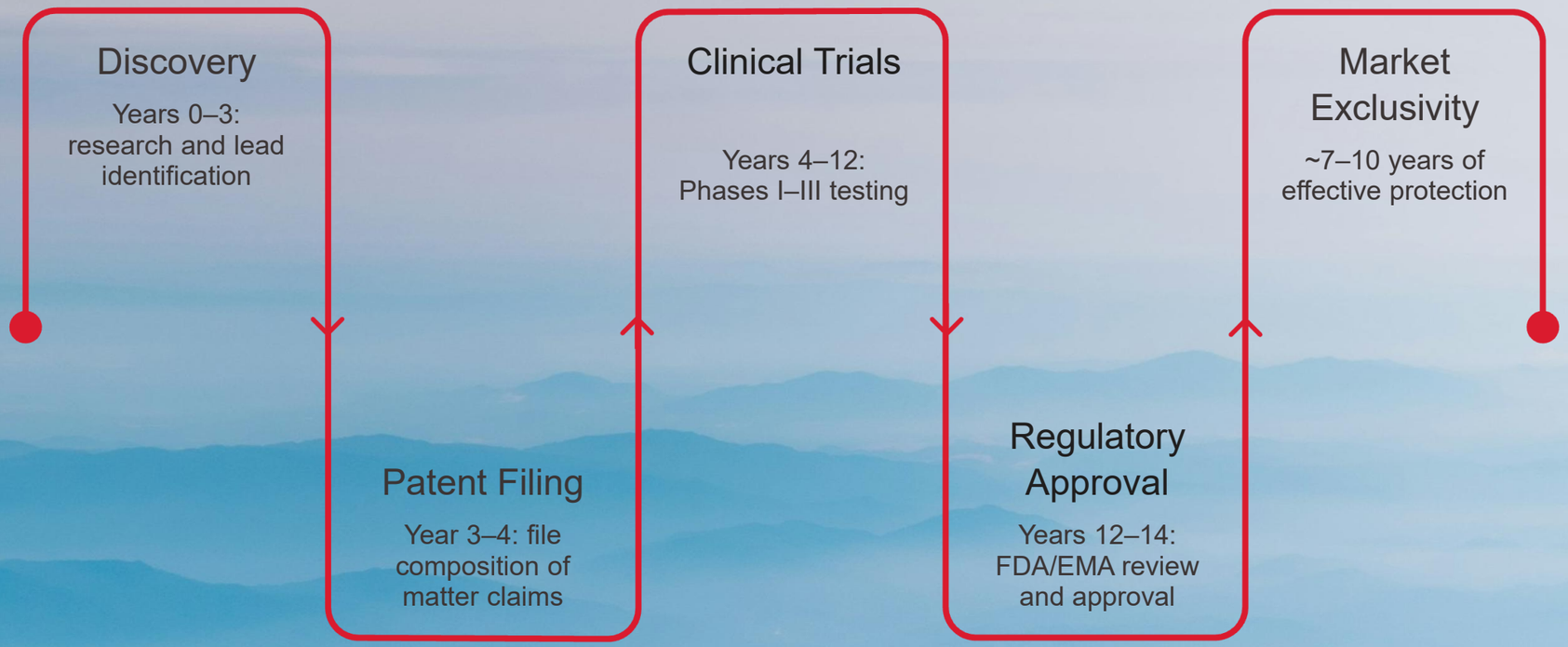
1. **Discovery Years 0–3**
   Research and lead identification
2. **Patent Filing Year 3–4**
   File composition of matter claims
3. **Clinical Trials Years 4–12**
   Phases I–III testing
4. **Regulatory Approval Years 12–14**
   FDA/EMA review and approval
5. **Market Exclusivity ~7–10 years**
   Effective protection

The 20-year patent clock starts at **filing** — not at approval. By market launch, effective exclusivity is compressed to just 7–12 years.

Development Timeline
Average time from discovery to approval

Patent Term
Exclusivity window designed to incentivise investment

Pharmaceutical Patent Lifecycle



The 20-year patent clock starts at **filing** — not at approval. By the time a drug reaches market, effective exclusivity is typically compressed to just **7–12 years**.

20-Year Term Starts at Filing

Years of clinical development silently consume patent life before a drug earns a single dollar of revenue.

Hatch-Waxman Patent Extension (US)

US law allows up to a **5-year Patent Term Extension (PTE)** to compensate for time lost during FDA regulatory review.

Paediatric Exclusivity Bonus

An additional **6-month extension** is granted beyond patent expiry for conducting qualifying paediatric studies.

Blockbuster Drugs & Patent Power

Lipitor — $13.7B/yr
Pfizer
Cholesterol — world's best-selling drug ever

Humira — $21.2B/yr
AbbVie
Autoimmune — highest annual sales in history

Keytruda — $20.9B/yr
Merck
Cancer immunotherapy — current blockbuster

Ozempic — $14.3B/yr
Novo Nordisk
GLP-1 agonist — reshaping diabetes & obesity care

Plavix — $9.3B/yr
BMS/Sanofi
Blood thinner — generic launch wiped 90% revenue

Sovaldi — $10.3B/yr
Gilead
Hepatitis C cure — ignited access debate worldwide

Patents Expire → Generics Enter → Prices Plummet → Access Soars.

The Patent Cliff: When Exclusivity Ends

A patent cliff occurs when a blockbuster drug loses exclusivity, triggering immediate and dramatic revenue loss. Generic competitors flood the market, prices collapse, and brand revenues can fall by up to **80% within just 3 months** of generic launch.

₹10T+

Lost Annually

Value wiped from pharma each year by patent cliffs

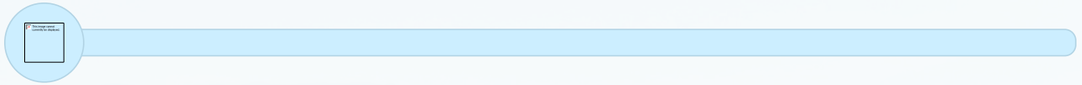
90%

Price Drop

Once multiple generics compete in the same market

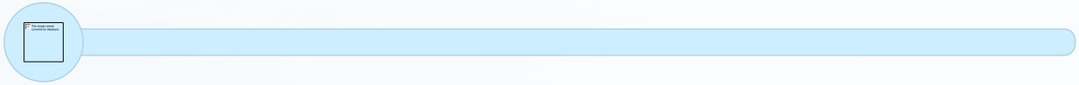
The "Great Patent Cliff" of 2015–2020

A historic wave of blockbuster drug patents expired in a compressed window — reshaping the competitive landscape of global pharma permanently.



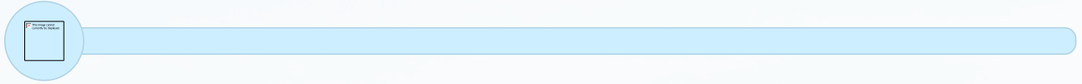
Pre-2015

Blockbusters at peak revenue — patent protection intact, generics held at bay



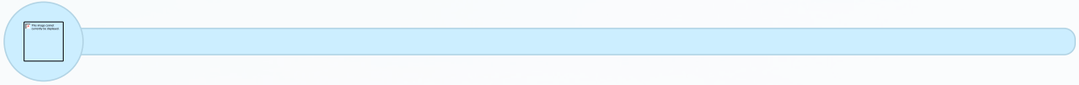
2015–2017

First wave of expirations — major drugs like Abilify and Sovaldi face generic competition



2018–2019

Accelerating cliff — Lyrica, Truvada, and other high-value brands lose exclusivity



2020

Peak impact — ₹200B+ in cumulative brand revenue eroded across the 5-year window

The Generics Revolution: Access at Scale

Generics now account for **90% of all U.S. prescriptions** filled — delivering the same therapeutic outcomes at 80–90% lower cost than brand drugs at launch.

₹20.4T

Saved in 2022

Saved by U.S. patients in 2022 alone

13

Months

Average FDA review time for generic approval (ANDA)

The Hatch-Waxman Act: Foundation of the Modern Generics Market

Landmark legislation signed into law in 1984, creating the legal and regulatory framework that made today's generics market possible. It balanced innovation incentives for brand manufacturers with a clear, accelerated pathway for generic entry.

Before Hatch-Waxman, generic manufacturers had to repeat full clinical trials — making market entry prohibitively expensive and slow.

> 90% of prescriptions. 13% of drug spend. Generics deliver extraordinary value — the same active ingredient, same dosage, same route of administration, at a fraction of the cost.

Evergreening: Extending the Monopoly

Pharmaceutical companies file SECONDARY patents to delay generic competition beyond the original patent term.

Formulation Patents

Same molecule,
new pill shape or coating

Dosing Patents

New dosing schedule
or extended release formula

Metabolite Patents

Patenting the active
form created in the body

New Indication

Same drug, new disease
or patient population

Case Study: Humira filed 136 patents — blocking biosimilars for 20 YEARS after original compound patent expired

The Generic Approval Pathway

Patent Expiry

Brand exclusivity ends

ANDA Filing

Generic manufacturer submits Abbreviated New Drug Application

FDA Review

13-month average review period

Market Entry

Rapid price competition begins

The ANDA pathway dramatically shortened generic approval timelines — enabling rapid market entry and near-immediate price competition that benefits patients and healthcare systems alike.

Impact Across the Ecosystem

Patients

Access life-saving treatments at 80–90% lower cost. ₹20.4T saved in the U.S. in 2022 alone — a direct quality-of-life improvement.

Payers & Systems

Insurers and national health systems redirect savings toward innovative therapies and expanded coverage, stretching every healthcare dollar further.

Brand Manufacturers

Patent revenue funds the next generation of R&D. The cliff is a forcing function — driving investment in biologics, specialty drugs, and novel mechanisms.

Challenges & the Road Ahead

While the generics model has delivered enormous value, emerging complexities threaten to slow its momentum.

Biosimilar Complexity

Biologics require more complex approval pathways — biosimilar uptake remains slower than traditional generics

Supply Chain Risk

Heavy reliance on offshore API manufacturing creates vulnerability to shortages and geopolitical disruption

Pay-for-Delay Tactics

Brand manufacturers settle patent disputes by paying generics to delay entry — reducing competition and keeping prices elevated

Biologics vs. Biosimilars: The New Frontier

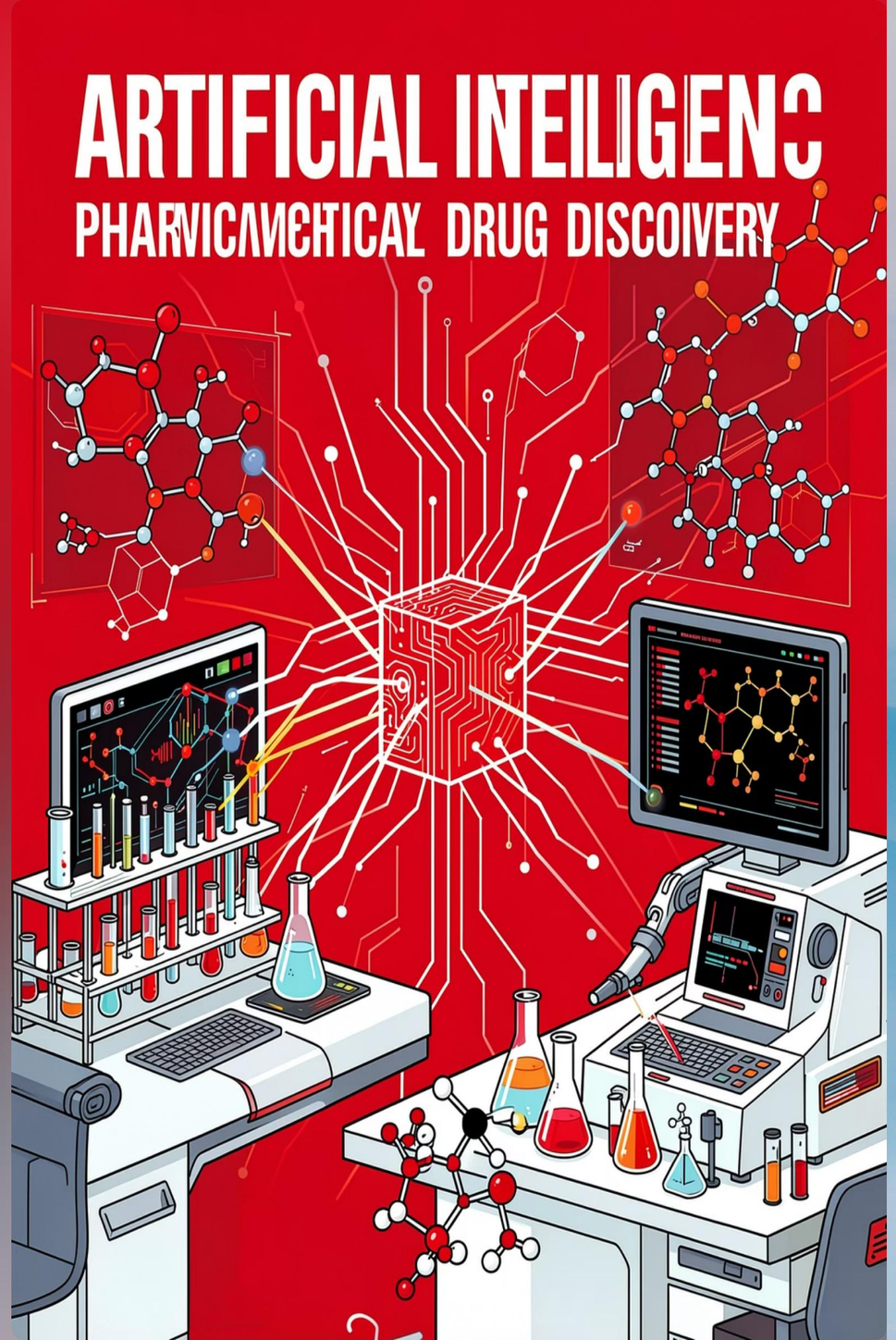
BIOLOGICS

- Living cell-derived medicines
- Highly complex molecules
- Cannot be exactly copied
- 12 years data exclusivity (U.S.)
- Cost: $10,000–$300,000/year
- Market: $400B+ and growing

VS

BIOSIMILARS

- Highly similar — not identical
- 30–60% lower cost typically
- Require clinical similarity data
- FDA approval pathway: 2010 BPCIA
- Could save $54B by 2027 (U.S.)
- Interchangeability still evolving



Briefing for Legal & Pharma Professionals

AI in Pharma: Accelerating Discovery & the Patent Dilemma

Navigating the intersection of artificial intelligence and intellectual property in modern drug development.

How AI is Transforming Pharma

Traditional drug discovery takes **years and billions of dollars** — AI is rewriting that equation entirely.

Target Identification

AI maps human biology to find disease markers with unprecedented speed and accuracy.

Generative Chemistry

Generative AI models *invent* novel molecular structures that bind to disease targets.

Predictive Success

Machine learning forecasts toxicity and clinical trial outcomes before lab entry.

The Impact

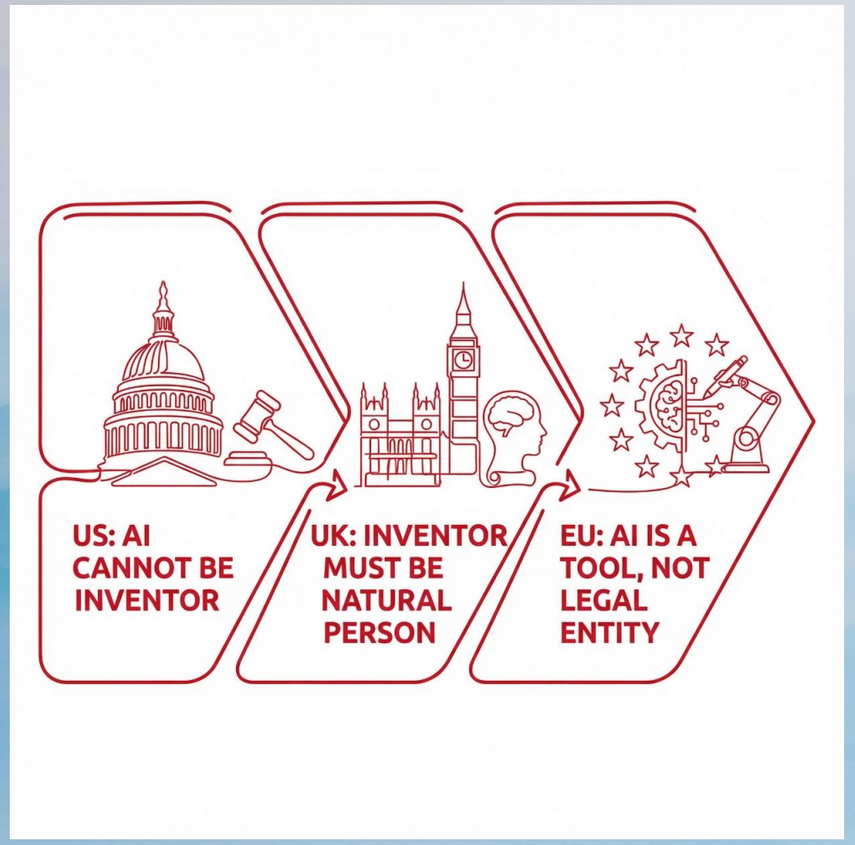
Discovery timelines shrink from **4–5 years to mere months**, transforming the industry.

The Patent Dilemma: The "Inventor" Problem

The Legal Reality

If an AI independently generates a novel drug molecule, can you patent it? Under current global patent law — in the **US, Europe, and the UK** — the answer is a strict **no** if the AI is listed as inventor.

A drug purely "invented" by AI without human intervention is technically **unpatentable** and falls into the public domain.



The DABUS Precedent: Courts across all major jurisdictions have universally ruled that an "inventor" must be a natural human being. AI is legally a tool — not an entity capable of holding rights.

How to Patent AI-Assisted Drugs Today

The strategy hinges on one critical legal concept: **significant human contribution.**

1

Prompt Engineering & Training

Demonstrate that human scientists designed the specific prompts and structured the training data.

2

Selection & Verification

Humans must recognise the utility of the AI's output and physically validate the molecule in a lab.

3

Position AI as a Tool

Frame the AI strictly as an advanced calculator — a sophisticated instrument used by the human inventor.

Conclusion & Future Outlook

Where We Stand Today

AI is the ultimate accelerator for drug discovery — but intellectual property laws are still catching up to the technology.

For now, **human ingenuity must remain central** to every patentable innovation.

What Comes Next

- **Legislative updates** are likely as AI autonomy increases globally
- Patent offices are actively developing new **AI-specific guidance**
- Companies that build **documented human workflows** today will be best positioned tomorrow

Key Takeaway

Always maintain a strong, well-documented "**human in the loop**" at every stage of AI-assisted drug development to secure and defend your intellectual property.

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