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Low Thresholds, High Walls: Novelty, Inventive Step, and the Structural Monopolisation of Knowledge in Biotechnology Patents: A Juridical–Empirical Content Analysis of 58 Granted Patents

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ABSTRACT

Background. Critics contend that the novelty and inventive-step thresholds in biotechnology patenting are applied so permissively that they enable a monopolization of foundational knowledge, yet permissive thresholds and concentrated ownership are seldom studied together.

Objective. This study aimed to measure, on one corpus of granted patents, how common threshold-stressing claim features are and how concentrated ownership is, and whether claiming differs by type of owner.

Methods. A doctrine-anchored content analysis covered fifty-eight granted biotechnology patents, purposively sampled and stratified across five domains from Google Patents. Each patent was coded from its title, abstract and first independent claim for six binary risk indicators and assignee metadata, and a blind second coder re-coded a random subsample (Cohen's κ = 0.632). Ownership was measured by assignee type, headquarters country and Herfindahl–Hirschman indices, and the risk index with non-parametric tests.

Results. Every patent carried at least one threshold-stressing feature (mean 2.14 of 6). Broad genus/functional claiming was near-ubiquitous (86%), whereas product-of-nature (12%) and diagnostic-correlation (9%) claims, the categories most constrained after Myriad and Mayo, were rare. Ownership was overwhelmingly high-income (96.6%; 56.9% United States) and corporate (77.6%), with no patent from a developing-country domestic industry. Risk indices were highest for universities and small firms rather than multinationals, although not significantly so.

Conclusion. In this sample, the knowledge-monopoly concern is better understood structurally than as single-firm dominance: functional and platform claiming combines with near-total geographic and corporate concentration. For net-importer jurisdictions such as Indonesia, the implications point to rigorous inventive-step and written-description examination, statutory exclusions and TRIPS flexibilities.

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1. Introduction

Biotechnology occupies the point where two of the hardest problems in patent law meet. One is the line between an invention and a discovery. The other is how far the resulting exclusive right should extend. Genes, proteins, cells, micro-organisms and the tools used to manipulate them lie close to the natural world, which puts pressure on the rule that a patentable invention must be new and non-obvious, not merely revealed. In *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013),[1] the United States Supreme Court held that isolated naturally occurring DNA is a product of nature and therefore not patent-eligible. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012),[2] it

struck down diagnostic claims that rested on natural correlations.[3] Many foundational biotechnology inventions, however, are research platforms, and whoever controls them can shape whole fields of downstream innovation, as the long contest over the CRISPR–Cas9 gene-editing tool shows.[4–6] A recurring criticism is that patent offices and courts have applied the novelty and inventive-step thresholds too permissively in this field. The result, on this view, is a monopolization of knowledge: broad exclusive rights over upstream science that end up in a few hands.[7]

This criticism is usually made at the doctrinal level, by reading leading disputes closely. Few studies test it against a systematic body of granted patents. An established empirical tradition does already map patent landscapes quantitatively, covering medical uses of known products,[8,9] medical machine learning,[10] cancer diagnostics[11] and messenger-RNA technologies.[12,13] That work shows that the drafting and ownership of biotechnology patents can be measured reproducibly from public records. Two questions are rarely examined together. How common are the claim features that the threshold critique treats as problematic, across ordinary granted biotechnology patents? And who owns the patents in which those features appear? At bottom, the monopoly argument concerns the joint distribution of low thresholds and concentrated ownership. The two are nonetheless usually studied apart.

This article takes up both questions at once. It treats the novelty and inventive-step problem as an observable property of the claims. Each patent is coded for a set of features that, under settled doctrine, set its subject matter or breadth against the patentability requirements. In parallel, the article measures how concentrated ownership is across assignee type and geography. The design is deliberately juridical–empirical. The coding categories come from patent doctrine, including the written-description and genus-claim jurisprudence recently synthesized by Karshtedt, Lemley and Seymore, 'The Death of the Genus Claim', 35 Harvard Journal of Law & Technology 1 (2021),[14] and the antibody-claiming paradox analyzed by Lemley and Sherkow, 'The Antibody Patent Paradox', 132 Yale Law Journal 994 (2023).[15] The questions behind the categories are legal. The answers, though, are quantitative and can be reproduced from public patent records.[16]

The Indonesian legal framework gives the inquiry practical weight. The 1945 Constitution[17] commits the state to several guarantees. Article 28C secures everyone's right to benefit from science and technology, Article 28H secures the right to health, and Article 33 calls for an economy organized for the greatest prosperity of the people. Law No. 13 of 2016 on Patents[18] puts these commitments into operation. It was recently amended by Law No. 65 of 2024,[19] and it implements the thresholds of Article 27 of the TRIPS Agreement[20] while keeping subject-matter exclusions in Articles 4 and 9. Yet Indonesia is a net importer of patented biotechnology. Rights granted elsewhere can be nationalized and enforced on its territory through the international system,[21,22] although its domestic sector produces almost none of the underlying science. More than 60% of pharmaceutical patent applications filed in Indonesia in 2024 reportedly came from foreign companies.[23]

The analysis rests on three questions. First, how widespread are threshold-stressing claim features in granted biotechnology patents, and by which mechanisms (product-of-nature, functional breadth, platform claiming) do they mainly operate? Second, how concentrated is ownership, and along which axis: single firms, corporate sector, or geography? Third, does the profile of threshold-stressing claiming vary with the owner of the patent? In particular, are broad upstream claims held mostly by multinational corporations, or by the universities and start-ups that generate foundational science? The study makes three contributions. It offers a reproducible juridical–empirical instrument that measures threshold pressure and ownership on a single corpus. It presents evidence that moves the binding constraint away from subject-matter eligibility and toward functional and written-description breadth. And it sets out *de lege ferenda* proposals calibrated to a net-importer jurisdiction.[24]

The rest of the article is organized as follows. The remainder of this Introduction sets out the legal framework of novelty and inventive step across the relevant systems, and the analytical link running from threshold application to monopoly. Section 2 states the materials and methods: the sampling logic, the coding instrument, the reliability procedure and the interpretive method. Section 3 reports the empirical results in two tables and three figures (Table 1 appears in Section 2). Section 4 discusses their doctrinal significance and contains the comparative analysis, three specific reform proposals for Indonesia, and the limitations of the study. Section 5 concludes.

1.1 Novelty and inventive step across systems

On paper, the patentability thresholds converge across the systems that matter for biotechnology. The TRIPS Agreement (Article 27) requires patents for inventions that are new, involve an inventive step, and can be applied industrially, though permitted exclusions remain. Indonesia implements these requirements through Law No. 13 of 2016. Article 5 defines novelty as the absence of the invention from the prior art. Article 7 demands an inventive step that a person skilled in the art would not find obvious. Articles 4 and 9 remove certain subject matter from protection: discoveries, mere new uses of known products, and living organisms other than micro-organisms. Law No. 65 of 2024 leaves Articles 5 and 7 in place, adjusts examination and procedural provisions, and widens the research (Bolar) exception. The European Patent Convention (Articles 52–57 and 53(b))[25] and United States law (35 U.S.C. §§ 101–103)[26] set out requirements that are materially similar. Divergent outcomes therefore arise from how the rules are applied, not from the statutory wording.[8]

In biotechnology, the standard itself is not the problem. Its application is. A naturally occurring molecule can be isolated, a sequence disclosed, or a natural correlation identified, and each can be presented as an 'invention' when it sits closer to a discovery. Claims may also be drafted in functional or genus terms that extend far beyond what was made or demonstrated. An incremental variant of a known product can likewise be styled as inventive. Each maneuver puts pressure on a different threshold. *Myriad* limits claims to isolated natural DNA. *Mayo* limits diagnostic claims that rest on natural correlations. The inventive-step and written-description doctrines limit overbroad functional and genus claims, and for the United States that limit was sharpened by *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023),[27,28] where a functional genus claim covering a whole class of antibodies failed for want of enablement.[3,29]

1.2 Thresholds and the monopolization of knowledge

The path from threshold application to monopoly is analytical. Permissive application of the thresholds has three effects. Subject matter near the natural commons is enclosed. Claims reach past the actual contribution and cover whole genera and functions. Foundational tools are captured by broad platform claims.[4] Each effect enlarges the scope of exclusion relative to the underlying inventive contribution, so each raises the toll that downstream researchers and producers must pay. Where the patents carrying these features are also concentrated, whether by sector or by geography, the aggregate result is a monopoly over a field of knowledge and over the capacity to work in it, not over a single product.[5,7,30] The access literature has long argued that developing countries, which consume patented biotechnology without originating it, carry the heaviest share of this burden.[31,32] This study measures both blades of that scissors at once.

Two theoretical lenses guide the reading of the data. The first is a positivist, formal-scope account. It treats the granted claim

as the measure of the right and asks only whether the statutory thresholds were met on their face. The second is a substantive, access-oriented account. It asks whether the scope of exclusion is proportionate to the disclosed contribution and to the public interest in a working commons.[24] The written-description and inventive-step doctrines operate exactly at the point where these two accounts diverge. This article argues that the monopoly problem now sits mainly there.[33]

The tension is more than conceptual. When breadth outruns contribution, the resulting rights raise the cost of every downstream use, and the burden falls hardest on actors that consume patented biotechnology without originating it. Recent access literature documents this for biotherapeutics and monoclonal antibodies, whose price and availability in low- and middle-income countries depend largely on the scope and licensing of upstream rights.[31,32] The COVID-19 experience sharpened the point. The distribution of vaccine and therapeutic technologies showed how the architecture of intellectual property shapes access in a crisis. It also showed that licensing design (exclusive or non-exclusive, pooled or bilateral) decides who can make and buy a given product.[24,34] A study that measures where threshold-stressing breadth sits, and who owns it, bears directly on the terms under which importer jurisdictions such as Indonesia can secure biotechnologies they do not produce themselves.

2. Methods

2.1 Research type and sampling

The study is juridical–empirical. A coding frame derived from doctrine is applied, as a structured content analysis, to a corpus of granted patents, and the resulting quantitative measures are then read against statute and case law. This design suits the research question, which has a legal side (how thresholds are applied) and an empirical side (reproducible observation of claims), in the manner of the patent-landscape studies now common in the biotechnology literature.[10,35] The sample contains fifty-eight granted patents taken from Google Patents. They cover five biotechnology domains selected to span the field's principal subject matters: recombinant DNA and genetic engineering (CPC C12N15); therapeutic antibodies and proteins (C07K16, A61K39/395); genome editing and nucleases (C12N9/22, C12N15/11); molecular diagnostics and biomarkers (C12Q1/68, G01N33); and vaccines, micro-organisms, cells and natural products (A61K39, C12N1/5/9, A01H). Sampling was purposive and stratified, not probabilistic, and this was deliberate. In each domain, distinct granted patents were selected to span assignee types: multinational corporations, small and mid-size firms, universities and public research organizations. Ownership variation is thus built into the sample, and the risk profile can be compared across owners. A probability sample of all biotechnology grants would give better population inference about prevalence. It would not guarantee the ownership variation that the third research question needs. The stratified design gives up some external validity to obtain the internal contrast required, and it probably over-represents public-sector and smaller assignees relative to a corporate-dominated population. Each patent was verified on its Google Patents page, and its patent number and URL appear in the published dataset. The assignee coded is the original assignee at grant. Two patents fell into two domains and were deduplicated, leaving fifty-eight unique records with grant years from 2002 to 2025.

2.2 Coding instrument

Every patent was coded from its title, abstract and first independent claim. Six binary novelty/inventive-step risk indicators were scored, each tied to a doctrinal concern as detailed in Table 1, and their sum forms a 0–6 risk index. Assignee metadata were also recorded: primary assignee, headquarters country and type, along with the number of claims. The index is descriptive and carries no validated weighting. Equal weights are the simplest transparent rule, the indicators are not assumed to be independent, and the prevalence of each indicator is reported separately in Section 3.2. The index counts how many distinct threshold-stressing features a claim shows. It is not a legal conclusion that any patent is invalid. Validity depends on facts and claim construction that a front-page reading cannot reach, so the indicators point to tension with the thresholds and do not decide it. The six indicators were derived deductively from the doctrinal literature. N1 comes from the product-of-nature line. N2 and N6 come from written-description and genus-claim doctrine. N3 comes from sequence-novelty analysis, N4 from *Mayo*, and N5 from the inventive-step and evergreening literature.[16,36] Coding from the front page was a deliberate choice. It is the one textual unit that is reproducible and comparable for every patent across jurisdictions, and since the study measures tension with the thresholds and not validity, it is a legitimate and conservative indicator.

Table 1. Novelty/inventive-step risk indicators and their doctrinal basis.

Code	Claim feature coded	Doctrinal concern
N1	Product of nature — isolated natural molecule / organism claimed	Discovery vs invention; *Myriad*; Arts. 4/9 UU 13/2016
N2	Broad genus / functional / result-oriented or %-identity claim	Inventive step & written description; overbreadth; *Amgen*
N3	Specific sequence claim (SEQ ID NO)	Novelty of sequence subject matter
N4	Diagnostic claim on a natural correlation	Patent-eligibility; *Mayo*
N5	Marginal / incremental improvement or new use of known product	Inventive step; evergreening; Art. 4 UU 13/2016
N6	Broad platform / research-tool claim	Scope vs contribution; upstream monopoly

2.3 Interpretive and comparative method

The doctrinal interpretation proceeds through four canons in turn. The grammatical canon reads the statutory text of Articles 5 and 7 of Law No. 13 of 2016 and Article 27 TRIPS. The systematic canon reads the thresholds together with the exclusions in Articles 4 and 9. The teleological canon looks to the purpose stated in the *naskah akademik* [academic paper accompanying the bill], which is to reward genuine invention while preserving the commons. The historical canon follows the shift from permissive early practice to the constraint imposed by *Myriad*, *Mayo* and *Amgen*. A worked application illustrates the method. Grammatically, Article 7 requires a step that is not obvious to the skilled person. Systematically, when read with the Article 4 exclusion of mere new uses, the requirement cannot be met by trivial recombination. Teleologically, a purpose of rewarding genuine contribution means that a functional claim extending beyond the worked example lacks the

required step. Historically, the tightening from broad permissiveness toward *Amgen*-style enablement scrutiny confirms the direction of change.[29] The comparison across the United States, the European Patent Convention and Indonesia follows functional equivalence in the sense of Zweigert and Kötz.[37] Systems are compared by how each resolves the same problem (the eligibility of natural subject matter and the control of claim breadth), not by matching rules according to their labels.[33]

2.4 Reliability

A blind second coder independently re-coded a random subsample of ten patents (sixty indicator judgments), working only from the codebook and the patent pages. Agreement reached 83.3%, with Cohen's $\kappa = 0.632$ (95% CI 0.42–0.84), which falls in the 'substantial' range of the Landis and Koch (1977)[38] benchmark. Agreement was high on the more factual indicators: product-of-nature, sequence and diagnostic claims each reached 90%. It was lowest on the two indicators that depend most on construction, namely broad functional claiming (80%) and platform claiming (70%). This gradient is a finding in its own right. Interpretive difficulty over patent-claim breadth is real, and it gathers where legal judgment, not fact, governs. The study's inferences are accordingly cautious about the marginal platform codes. The headline results do not depend on the contested items: the universality of at least one threshold feature, the dominance of functional claiming, and the ownership concentration.

2.5 Analysis and ethics

Ownership concentration was measured through counts and shares by assignee type and headquarters country, and through Herfindahl–Hirschman indices (HHI) at the firm and country levels. These were read against the conventional competition-policy benchmarks, under which values below 1,500 indicate an unconcentrated structure and values above 2,500 indicate high concentration. The risk index was compared across assignee types and domains with the Kruskal–Wallis test, across the corporate/public divide with the Mann–Whitney U test, and against claim count with Spearman correlation. Because the sample is small, effect sizes (epsilon-squared and rank-biserial correlation) are reported next to the p-values, with $\alpha = 0.05$. The study analyzes publicly available patent documents. It involved no human subjects, so no ethical approval was required, and none is claimed.

A scripted, reproducible pipeline carried out all analyses. The script that generates every statistic and figure reported below is supplied with the article, along with the coded dataset and the blind reliability key. Each number in the results can therefore be traced to its source.

3. Results

3.1 Ownership concentration: structural, not single-firm

Ownership is concentrated, though along sector and geography, not along the individual firm, as detailed in Table 2 and visualized in Figure 1. At the firm level the sample is dispersed. It contains fifty-one distinct assignees, a firm-level HHI of only 214 (well within the unconcentrated range) and a top-five share of 17.2%, so no single corporation monopolizes the field. The concentration is structural. Corporate entities hold 77.6% of the patents (multinational corporations alone 53.4%), against 22.4% for universities and public bodies. The geographic imbalance is clear. Of the assignees, 96.6% are headquartered in high-income economies, with the United States alone accounting for 56.9%, and the country-level HHI of 3,448 lies well inside the highly concentrated range. No patent in the sample originates from a developing-country domestic industry, and the only two non-high-income assignees are public research academies. Figure 1 shows that the Global South, and Southeast Asia in particular, is absent as an originator of the knowledge these patents enclose. It appears only as a territory where the rights can be nationalized and enforced.[21,31]

Table 2. Ownership concentration of the sample (N = 58).

Dimension	Measure	Value
Distinct assignees	count	51
Firm-level Herfindahl–Hirschman index	0–10,000	214
Top-5 assignee share	%	17.2
Corporate ownership (MNC + SME)	%	77.6
Multinational-corporation ownership	%	53.4
University / public ownership	%	22.4
High-income-economy assignees	%	96.6
United States assignees	%	56.9
Country-level Herfindahl–Hirschman index	0–10,000	3,448
Developing-country domestic-industry patents	count	0

Note. University/public ownership (22.4%) comprises 12 university and public-research patents plus 1 government patent (see Table 3). Corporate ownership comprises multinational corporations and small and mid-size firms.

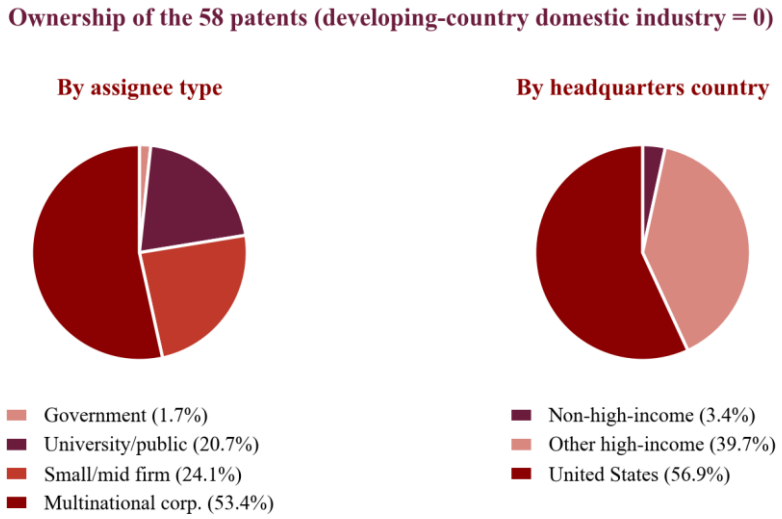

Figure 1. Ownership of the 58 patents by assignee type (left) and headquarters country (right).

3.2 Threshold-stressing claiming is pervasive

Every patent in the sample carries at least one threshold-stressing feature, and the average patent carries just over two (mean 2.14 of 6, SD 0.78). The mechanisms are very unevenly distributed, however, as Figure 2 shows. Broad genus, functional or result-oriented claiming is near-ubiquitous at 86% (50 of 58 patents). This drafting technique reaches past the actual contribution to cover a class defined by what it does or by a similarity threshold. Specific sequence claiming (43%, 25 of 58) and broad platform or research-tool claiming (41%, 24 of 58) come next, and marginal-improvement or new-use claiming appears in 29% (17 of 58). The two features most directly curtailed by recent eligibility jurisprudence are comparatively rare. Product-of-nature claims to isolated natural molecules appear in only 12% (7 of 58) of patents, and diagnostic claims on natural correlations in only 9% (5 of 58). The pattern in Figure 2 suggests that the post-*Myriad* and post-*Mayo* constraints have taken effect on the categories they targeted.[3,39] Threshold pressure appears to have moved to functional and platform breadth, through which it now operates almost entirely. Those cases did not reach this mechanism, and *Amgen* has only begun to address it.[29] The risk index and claim count are uncorrelated (Spearman $\rho = 0.09$, $p = 0.49$). Breadth-related risk is therefore a property of how claims are drafted, and not merely of how many are filed.

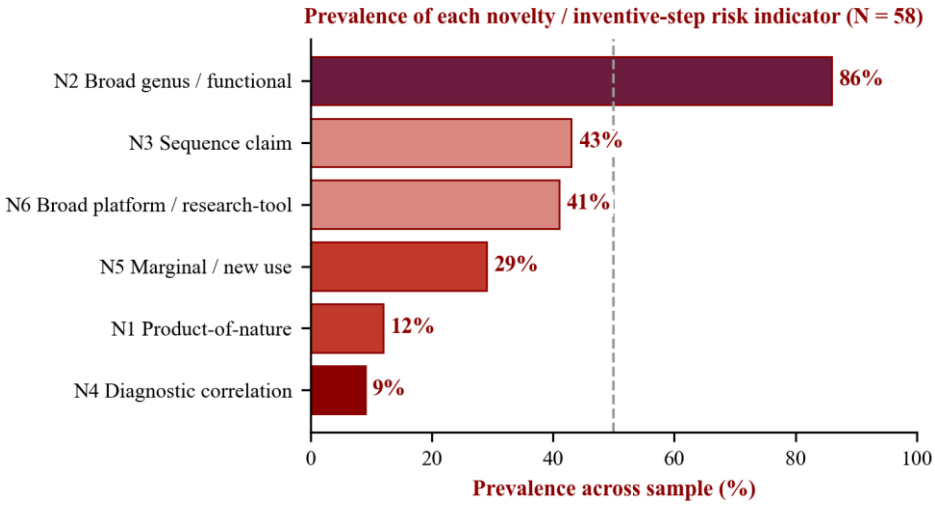

Figure 2. Prevalence of each novelty/inventive-step risk indicator (percentages shown; N = 58). The dashed line marks 50%.

3.3 Who holds the broadest claims?

The distribution of threshold-stressing claiming by owner runs against the intuition that multinational corporations are the principal offenders, as Table 3 and Figure 3 show together. The risk index is highest for university and public patents (mean 2.42, n = 12) and for small firms (2.29, n = 14). It is lowest for multinational corporations (1.97, n = 31). Pooling the public sector gives a mean of 2.38, against about 2.07 for the pooled corporate group (small and mid-size firms plus multinational corporations, computed from Table 3). On the corporate-versus-public contrast the difference approaches significance (Mann–Whitney $p = 0.08$, rank-biserial ≈ 0.28), and the Kruskal–Wallis test across all four types is not significant ($H = 5.8$, $p = 0.12$, $\varepsilon^2 \approx 0.10$). Figure 3 suggests a possible explanation, which this study did not test. The broadest, most platform-like biotechnology patents may often be the foundational ones produced in universities and start-ups, such as the genome-editing, expression-system and antibody-platform patents, and their claims are drafted to capture an entire tool.[4] Domain differences run the same way, as the right-hand panel of Table 3 records. Therapeutic-antibody patents tend to be defined by

specific targets and sequences and carry the lowest risk (mean 1.58). Diagnostics and vaccine/natural-product patents carry the highest (2.33 each), although the domain differences are not statistically significant (p = 0.08). The breadth relevant to monopoly power thus appears to sit at the upstream, foundational end of the value chain. Public-sector and start-up inventors dominate that end, and the licenses that govern whole fields are issued from it.[5,6]

Table 3. Novelty-risk index by assignee type and by domain.

Assignee type	n	Mean	Domain	n	Mean
University / public	12	2.42	Diagnostics	12	2.33
Small / mid firm	14	2.29	Vaccines / natural products	12	2.33
Government	1	2.00	Genome editing	10	2.30
Multinational corp.	31	1.97	Recombinant DNA	12	2.17
—	—	—	Therapeutic antibodies	12	1.58
All patents	**58**	**2.14**	**All patents**	**58**	**2.14**

Note. Grand mean = 2.14 (SD 0.78). Kruskal–Wallis across types H = 5.8, p = 0.12, $\varepsilon^2 \approx 0.10$; corporate vs public Mann–Whitney p = 0.08, rank-biserial ≈ 0.28; across domains p = 0.08.

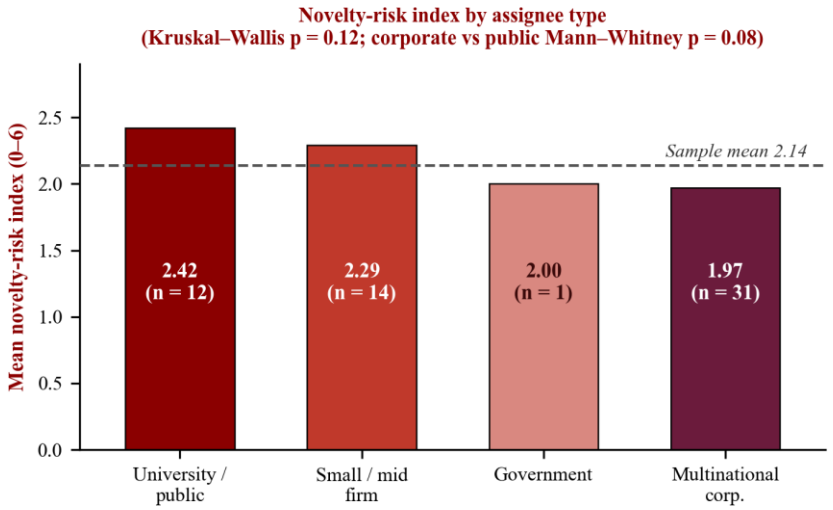

Figure 3. Distribution of the novelty-risk index by assignee type.

Taken together, the three results describe a single structure. Threshold-stressing claiming is universal, but it is channeled overwhelmingly through breadth, not through the enclosure of nature. Ownership is dispersed at the level of the firm yet highly concentrated at the level of the sector and the country. The broadest claims sit upstream, with the public-sector and start-up inventors who generate foundational platforms. The firm-level dispersion (HHI 214) and the country-level concentration (HHI 3,448) do not conflict. Many different organizations hold these patents, but nearly all are located in the same handful of high-income economies. The breadth they command is generated at the foundational stage and consolidated downstream through exclusive licensing. Section 4 interprets this configuration of dispersed holders, concentrated geography and upstream breadth.

4. Discussion

4.1 Interpretation of the findings

The two measurements do more than confirm the monopoly-of-knowledge thesis; they refine it. In one specific sense the threshold critique is empirically well founded. Every granted patent examined shows at least one feature that sits uneasily with strict application of the patentability requirements, and the field average is two, as Figure 2 records. The mechanism, however, differs from the one the leading cases foreground. Claims to products of nature and to diagnostic correlations, the targets of *Myriad* and *Mayo*, are now comparatively rare, which suggests that eligibility doctrine has constrained the categories it addressed.[3,39] Pressure on the thresholds now runs through functional and genus breadth and through platform claiming. These techniques widen scope relative to contribution without claiming nature as such, and neither eligibility case reached them directly. *Amgen* has begun to discipline the antibody genus, yet the broader field of functional claiming stays comparatively open.[28,29,40] If the thresholds are being applied too permissively, the pattern points to inventive step and written description, rather than subject-matter eligibility, as the areas needing closer scrutiny.

This relocation has a doctrinal payoff. Read for their *ratio decidendi*, *Myriad* and *Mayo* both turn on the pre-emption of a natural thing (an isolated gene, a metabolic correlation). Both leave untouched the situation in which an applicant claims not nature itself but a functionally defined class that reaches far beyond the worked example. *Amgen* addressed exactly this move for antibodies by requiring that the full scope of a functional genus be enabled. The emerging response has been to re-engineer antibody claims around structurally defined paratopes supported by comprehensive experimental data.[29] Eligibility doctrine has spent its enforcement energy on the channel the earlier cases named, while the channel they did not name has stayed comparatively open. This is what the prevalence data in Figure 2 reveal.

The ownership findings recast 'monopoly' as a structural phenomenon rather than a firm-level one. No single corporation

dominates, and the firm-level HHI of 214 is low. What is concentrated is the sector and the geography. More than three-quarters of the patents are corporate and more than half belong to multinational corporations, but the sharper concentration is spatial. Almost all originate in high-income economies, a majority in the United States, and none in any developing-country domestic industry, as Table 2 sets out.[31,32] The antibody market shows the same pattern: a 2026 dataset of 1,732 patents covering 63 monoclonal antibodies reports that a handful of firms lead production, and that market concentration and high prices raise equity concerns.[30] For a jurisdiction such as Indonesia, the significance is immediate. Its patent law applies the same thresholds as the offices that granted these patents, and through the international system those rights can be obtained and enforced on its territory. Yet its domestic sector appears nowhere among the originators.[21,22] In this sample, then, the patented subject matter is held almost entirely in high-income economies, and where the rights are in force the Global South can use it only under license. Whether this amounts to a monopoly of knowledge depends on the licensing and enforcement position of each right, which was not measured.[33]

The tendency for the broadest claiming to sit upstream, in universities and start-ups, is counter-intuitive and appears in Figure 3, although the differences are not statistically significant. It sharpens the policy question. Broad public-sector and start-up patents are tempting to read benignly, as the natural form of foundational science. Yet the breadth of foundational platform patents is what converts a scientific advance into control over a field, and such patents are routinely exclusively licensed to, or acquired by, the same corporations that dominate the downstream.[4–6] The CRISPR–Cas9 field illustrates the pattern: three groups hold the foundational patents, and third parties find it hard to decide where to obtain licenses.[5,6] Breadth originates upstream, and the monopoly consolidates downstream. The two findings are two faces of one value chain. The upstream locus is, in part, a predictable product of technology-transfer incentives rather than an accident of where science happens: under the Bayh–Dole model and its global diffusion, university licensing offices are rewarded for broad claiming and exclusive licensing.[7,41] A threshold policy aimed at the monopoly problem should therefore concentrate on inventive-step and written-description scrutiny of functional and platform claims at the foundational stage. Subject-matter eligibility has already done much of the work it can do.

For access-oriented jurisdictions, the implications are practical. They follow from the mechanism the study identifies, not from the one the debate usually assumes. Several instruments bear on claim breadth: rigorous examination of functional breadth and platform scope at the national phase, firm use of the exclusions in Articles 4 and 9 of Law No. 13 of 2016, and readiness to deploy the flexibilities the TRIPS framework preserves (research exceptions, compulsory licensing under Articles 30–31, and strict written-description requirements).[24,42] A 2026 review of 149 compulsory-license instances recorded between 2001 and 2024 found that 61% were executed and that the flexibilities were used to facilitate access to medicines.[43] Non-exclusive public-health licensing, as operated through pooled mechanisms during the COVID-19 crisis, offers an additional route for widening access once rights exist.[31,34] Exhortation about gene patents addresses a channel that doctrine has already narrowed. The open channel is claim breadth.

Two caveats keep the reform argument honest. First, examination reform bears on rights not yet granted. For the large stock of already-granted patents that reach Indonesia through the international system, the operative instruments come after grant: opposition, invalidation on written-description grounds, and the TRIPS flexibilities. Non-exclusive public-health licensing through pooled mechanisms widened access to COVID-19 therapeutics and is now being extended to monoclonal antibodies. It is an additional route that operates on existing rights rather than on the examination that created them.[32,34] Second, the political economy of these flexibilities is real. Indonesia's earlier government-use actions on antiretroviral medicines drew considerable trade attention and are recorded among the compulsory-licensing episodes of the post-Doha period,[44] and negotiated voluntary licensing has in several instances delivered access more quickly and with less friction than compulsory measures.[31,42] A reform package that pairs demanding examination of future functional claims with a transparent, rule-based protocol for deploying flexibilities against the existing stock is therefore better calibrated to a net-importer jurisdiction than either instrument alone.

4.2 Comparative practice: United States, Europe, and Indonesia

The United States, the European Patent Convention and Indonesia share similar statutory thresholds. They differ mainly in how those thresholds are applied, so the comparative lesson concerns practice rather than text. In the United States, the courts have supplied the corrective. *Amgen* and the written-description line of authority have started to restrain functional genus claiming, and patent applicants have answered by drafting narrower and better-supported claims.[28,29,40] Europe imposes comparable discipline at an earlier stage. Sufficiency and support objections arise during examination and opposition, and this explains why European medical-use practice developed its own distinctive claim formulations.[9] India supplies a third comparator. Its efficacy-based screening under Section 3(d) is a deliberate statutory brake on incremental claiming, and several commentators treat it as a model for reconciling patent protection with public-health need.[33] Indonesia lies between these poles. Its text matches the others, yet no settled body of practice has so far emerged to restrain functional breadth at the national phase.

For the Indonesian examiner, the implication is that the necessary tools already sit within the statute. Reading the inventive-step requirement of Article 7 purposively and demanding, and applying the Article 4 and 9 exclusions with rigor, would permit closer scrutiny of upstream functional and platform claims with no amendment at all. As the reform proposals below argue, an amendment would nonetheless fix the practice in law and make it less dependent on the disposition of individual examiners. The comparative record points in one direction. Where scrutiny is applied steadily, whether by courts as in the United States or by examiners as in Europe, the breadth of granted claims narrows toward the actual contribution.

4.3 De lege ferenda: three proposals for Indonesia

Three reforms follow, and each names the instrument, the actor and the legal basis. First, at the legislative level, the DPR should add to Law No. 13 of 2016 an explicit written-description proviso. It would require the scope of a functional or genus claim to match the disclosure that enables it, reflecting the substance of the rule that United States law now applies through *Amgen* and that European practice applies through Articles 83 and 84 EPC. The constitutional basis is Article 28C of the 1945 Constitution, and the statutory anchor is the inventive-step requirement of Article 7.[29] Second, at the regulatory level, the Directorate General of Intellectual Property (DJKI) should revise its substantive-examination guidelines. The revision would call for closer scrutiny of broad platform and result-oriented claims in biotechnology and would put into operation the Article 9 exclusions and the industrial-applicability limb of Article 27 TRIPS.[33] Third, at the institutional level, the government should adopt a standing protocol for the disciplined use of TRIPS flexibilities. This would comprise a statutory research exception and a streamlined compulsory-licensing pathway for public-health need, grounded in Article 33 of the 1945 Constitution and Articles 30–31 of TRIPS and informed by the political economy of Indonesia's earlier government-use actions.[24,42] Taken together, these measures address the breadth

mechanism that the data identify. They do not address the eligibility channel, which the debate has already largely resolved.

4.4 Limitations

Five limitations bound these claims. First, the risk indicators show tension with the patentability thresholds on a front-page reading. They are not determinations of validity, which depends on the full specification, the prosecution history and claim construction. The reliability is good but short of perfect (κ = 0.632), and it is concentrated on the breadth judgments, which marks the zone where that reading is most open to challenge. Second, the sample comprises fifty-eight patents, purposively stratified for variation in domain and ownership. It is not a probability sample of all biotechnology grants, so the concentration figures in Table 2 describe this constructed sample. Even so, the complete absence of developing-country industry among fifty-one distinct assignees is a strong signal. Third, ownership is coded at the level of the assignee organization and not the ultimate parent. Grouping by parent would raise the concentration measures, so the reported firm-level dispersion is a conservative bound. Fourth, patents prosecuted at the United States office dominate the sample, and the application of thresholds differs across offices. The migration-of-pressure thesis is therefore best evidenced for the United States and is framed as a hypothesis for the European and Indonesian systems. Fifth, there was a single primary coder and a reliability subsample of ten patents, so the κ estimate is itself imprecise (95% CI 0.42–0.84). The natural next step is to double-code the full corpus, extend the instrument to a probability sample with full-text claim coding, and pair it with national-phase-entry data for Indonesia and its neighbors.

5. Conclusion

On the same fifty-eight granted biotechnology patents, this article measured two things: how often claim features stress the novelty and inventive-step thresholds, and how concentrated ownership is. Inter-coder reliability was substantial (κ = 0.632). Threshold-stressing claiming appears in every patent in the sample and averages 2.14 features per patent. It works mainly through broad functional and platform claiming (86% and 41%), and much less through the product-of-nature (12%) and diagnostic (9%) claiming that recent eligibility cases curtailed. No single firm monopolizes ownership. Yet ownership is structurally concentrated: 77.6% corporate, 96.6% high-income and 56.9% United States, with no developing-country industry assignee. In this sample, the knowledge-monopoly concern therefore finds support, but the usual account appears to place it in the wrong spot. The binding mechanism is claim breadth at the foundational, upstream end of the value chain. There, universities and start-ups generate the broadest platform claims, and dominant corporations later consolidate them downstream. The concentration that matters is geographic and sectoral, not firm-specific. For net-importing jurisdictions such as Indonesia, three levers fit this mechanism: a written-description proviso enacted by the DPR, heightened examination of functional and platform claims by the DJKI, and a standing protocol for TRIPS flexibilities grounded in Article 33 of the Constitution. A debate about gene patenting, which doctrine has already largely resolved, fits it poorly.

Three lines of further work follow directly. A probability sample of biotechnology grants with full-text claim coding would turn the prevalence signals reported here into population estimates. Double-coding the entire corpus would sharpen the reliability of the breadth indicators, on which the argument depends most. Linking the patent data to national-phase-entry records for Indonesia and its ASEAN neighbors would show which of these enclosing rights actually reach the jurisdiction, and by which routes. If all three were pursued, the present study (an instrument, a reliability profile and a set of descriptive findings) would grow into a fuller account of how the structural monopoly of upstream biotechnology bears on access in the Global South.

Declarations

Ethics Approval and Consent

Not applicable. The study analyzed publicly available patent documents and involved no human participants or animals, so ethics committee approval and informed consent were not required.

Consent for Publication

Not applicable.

Use of Artificial Intelligence

None. No artificial intelligence tools were used to generate, analyze or write any part of this work.

Author Contributions

R.H.: Conceptualization, Methodology, Investigation, Formal analysis, Writing – original draft. I.A.: Methodology, Validation, Data curation, Writing – review & editing. K.A.: Resources, Visualization, Supervision, Writing – review & editing. All authors reviewed and approved the final manuscript.

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Data Availability

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