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Patent Cliffs as Contestable Markets: Biosimilar Entry and Forecast Erosion of Originator Value

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Abstract

The patent cliff is usually studied through prices and uptake. We instead treat it as a contestable-markets problem and study the supply of entrants. Combining a global biosimilar pipeline (823 development programmes, 283 developers, 99 reference molecules) with a loss-of-exclusivity table and a long-horizon (2025–2046) worldwide sales forecast, we ask whether contestable rent attracts entrants and whether developer crowding predicts steeper forecast erosion. First, the contestability prediction holds only weakly: distinct developer counts rise with originator peak sales, but the elasticity is small and only marginally significant in the preferred negative-binomial model ($\beta = 0.147$, $p = 0.076$); even at the upper end of its 95% confidence interval, doubling the rent raises developer counts by no more than about 24%. Second, in a smaller erosion sample ($N = 31$), developer crowding is associated with a steeper forecast erosion slope: each additional developer is associated with a steeper projected post-expiry decline ($\beta = -0.003$, $p = 0.015$; $p \approx 0.023$ with small-sample t inference). The sample covers only near-cliff molecules, so the association is descriptive, not causal. Descriptively, about two-thirds of biosimilar launches occur within one year before to three years after patent expiry. Because rents and erosion are forecast-derived, we frame the study as a test of how a commercial forecaster encodes the economics of contestable patent cliffs. The results qualify the contestable-markets view of biologics: entry responds to opportunity only weakly, but conditional on entry, crowding is associated with steeper forecast erosion of originator value.

JEL classification: L11, L65, I11, O34, G31

1 Introduction

When a blockbuster biologic loses exclusivity, a large stream of rents becomes legally contestable, and for biologics the contestants are biosimilars rather than small-molecule generics. The economics of that transition is usually examined through two lenses: how far prices fall, and how quickly volume shifts to entrants. A third, more fundamental, lens is comparatively neglected — the supply of entrants itself. How many developers show up, when, and with what consequence for the originator's value?

This paper takes that lens. The theory of contestable markets (Baumol et al., 1982) predicts that large rents protected only by soon-expiring barriers should attract entry, and that the threat and reality of entry should discipline incumbent rents. Applied to the patent cliff, the theory yields sharp, testable predictions: entrant counts should rise with contestable rent; entry should cluster around the fall of the barrier; denser entry should erode the incumbent's rents faster; and the composition of entrants should reflect who can profitably contest the largest opportunities. We formally test the first and third of these predictions (H1 and H2) and report descriptive evidence on the second (entry timing); entrant composition is left for future research.

We combine three sources. A global biosimilar pipeline records 823 development programmes by 283 distinct developers against 99 reference molecules, with each programme's developer, region, drug class and highest phase. A loss-of-exclusivity (LOE) table supplies originator 2024 worldwide sales and US and

ex-US patent-expiry dates for the largest biologics. A long-horizon worldwide sales forecast (2025–2046) supplies originator rents and projected post-expiry revenue trajectories, from which we derive an erosion slope for each molecule with a usable expiry date. The reference-molecule generic name joins the pipeline to originator economics, enlarging the entry sample (N = 71) beyond the molecules covered by the LOE table alone; the erosion sample (N = 31) is limited to molecules with an LOE expiry date.

As with any forecast-based study, we are explicit about the estimand. Originator rents and erosion slopes are model outputs, so our erosion tests ask whether forecasters build steeper declines where entry is denser, not whether realised revenue falls faster. This is a relevant object for valuation and deal-making, where such forecasts inform the value attributed to assets facing a cliff; validating the forecasts against realised post-expiry revenue is beyond the scope of this paper.

Preview of findings. The contestability prediction survives only in weak form: entrant counts rise with rent, but the elasticity is small and statistically fragile, and entrant counts also vary by drug class. Crowding is associated with steeper forecast erosion — the paper's central result — and the sign is preserved when class fixed effects are dropped. Entry is concentrated around patent expiry. Together these refine, rather than confirm, a naïve contestable-markets reading of the biologic patent cliff.

Contribution. We provide a molecule-level analysis of 99 reference molecules that separates two margins of contestability. The entry margin asks how strongly the size of the economic opportunity predicts the number of developers. The erosion margin asks how developer crowding relates to the forecast decline in the originator's revenue. Prior biosimilar work mostly links entry to prices or uptake; we link the supply of entrants to contestable rent and to a forecast erosion slope. Our evidence suggests that the contestable-markets lens fits the erosion margin (crowding is associated with steeper forecast erosion) better than the entry margin (the association between rent and developer counts is positive but modest). The remainder of the paper proceeds as follows: Section 2 reviews the literature and develops hypotheses; Section 3 details data and method; Section 4 reports results; Section 5 reports robustness; Section 6 discusses; Section 7 states limitations; Section 8 concludes.

2 Literature and Hypotheses

2.1 Contestable markets and entry

The theory of contestable markets holds that what disciplines prices is not the number of incumbents but the ease of entry and exit: with low barriers and sunk costs, even a concentrated market behaves competitively because potential entrants can hit and run (Baumol, 1982; Baumol et al., 1982). Empirical tests of contestability are mixed; Morrison and Winston (1987) found that airline markets are imperfectly contestable, while Bergman and Rudholm (2003) distinguished potential from actual competition in the Swedish pharmaceuticals market and found that both shape brand-name price paths. A patent cliff is a natural laboratory for the theory: the barrier (the patent) has a known expiry, and the contestable rent (originator sales) is observable.

2.2 Patent expiration, entry and price erosion

A large literature studies generic entry after small-molecule patent expiry. Caves et al. (1991) established the canonical facts on entry and price erosion; Scott Morton (1999) modelled the entry decision and showed entry rises with market size; Reiffen and Ward (2005) documented how the number of entrants drives the depth of price decline, and Grabowski and Kyle (2007) related the timing of generic entry to the originator's market exclusivity period. Scott Morton and Kyle (2011) synthesise the evidence that generic entry is greater in larger markets and that more entrants produce steeper price drops. Our erosion hypothesis ports this "more entrants → faster erosion" logic from small-molecule prices to biologic revenue forecasts.

Related work in this journal examines demand spillovers at patent expiry (Zimmer, 2018), brand payoffs from pay-for-delay settlements (Saha & Xu, 2023) and the competitive effects of pseudo-generics (Rodrigues et al., 2014).

2.3 Biosimilars: a slower, more contested cliff

Biologics differ from small molecules in ways that blunt contestability. Biosimilars face higher development and manufacturing costs, lack automatic substitutability absent an interchangeability designation, and confront physician inertia and buy-and-bill incentives, so erosion is typically slower than the precipitous small-molecule cliff (IQVIA, 2024; IQVIA Institute, 2023). Evidence on realised biosimilar markets is consistent with both margins mattering. In Europe, market features and procurement policies predict biosimilar entry, prices and penetration (Scott Morton et al., 2018). In US Medicare Part B, each additional biosimilar competitor is associated with a 10–13% fall in the originator's price ratio (Jofre-Bonet et al., 2025), and originators respond to biosimilar entry by cutting net-of-rebate prices to retain volume, unlike small-molecule incumbents facing generics (Feng et al., 2026). The 2023 US adalimumab (Humira) episode shows that entry timing can depart from patent expiry: biosimilar entry was timed by negotiated patent-litigation settlements rather than by the expiry of the core patent alone (IQVIA Institute, 2023). For biologics, therefore, the supply of entrants — not just the fact of expiry — plausibly shapes the erosion path, motivating our focus on entrant counts.

2.4 Racing, crowding and rent dissipation

Whether crowding dissipates or merely reallocates rents is contested. Cockburn and Henderson (1994) found limited support for strong rent-dissipation in drug discovery, while Krieger (2021) shows that drug developers learn from competitors' R&D failures when deciding whether to continue projects, so competitive density carries informational as well as rivalrous content. In the biosimilar cliff, crowding plausibly both signals a contestable opportunity and accelerates share and price erosion; we test the erosion prediction.

2.5 Research gap

Two gaps motivate the study. First, much of the biosimilar evidence concerns prices or uptake (e.g., IQVIA, 2024; IQVIA Institute, 2023), not the supply of entrants as a function of contestable rent. Second, the link from entrant intensity to a forecast erosion slope — a quantity directly relevant to valuation — is rarely estimated across many molecules. We address both.

2.6 Hypotheses

H1 — Rent attracts entrants

Contestable-markets theory and the generic-entry literature predict that larger contestable rents attract more entrants (Baumol et al., 1982; Scott Morton, 1999). Mechanism: expected post-entry profit rises with the size of the rent pool, drawing more developers. Three related but distinct forces are at work: the economic attractiveness of the market, the feasibility and cost of entering it, and the competitive consequences of multiple developers pursuing the same molecule. H1 tests only the first; we treat entry cost and feasibility as candidate explanations for any shortfall, not as tested mechanisms. H1: the count of distinct biosimilar developers per reference molecule increases with originator peak worldwide sales.

H2 — Crowding steepens erosion

Porting the small-molecule result (Reiffen & Ward, 2005; Scott Morton & Kyle, 2011) to biologics, more credible entrants should produce faster share and price erosion, which a forecaster encodes as a steeper projected post-expiry decline. H2: higher developer crowding predicts a steeper (more negative) forecast erosion slope for the originator.

3 Data and Methodology

3.1 Sources and unit of analysis

The unit of analysis is the reference molecule. From the global biosimilar pipeline we aggregate, per molecule: the count of distinct developers (the entrant count), a clinical-stage entrant count (excluding preclinical), and the modal drug class. From the LOE table we take originator 2024 worldwide sales and US and ex-US patent-expiry dates for the largest biologics; these expiry dates anchor the post-expiry window used for the erosion slope. From the 2025–2046 worldwide sales forecast (Evaluate) we take, per originator (matched by generic name), peak worldwide sales (the contestable rent) and the projected revenue trajectory, from which we compute the erosion slope.

Generic names are lowercased and stripped for joining. No imputation is performed; each model uses listwise-complete cases.

Sample construction proceeds in three steps. The pipeline covers 99 reference molecules, all of which enter the descriptive statistics. Of these, 71 can be matched by generic name to an originator peak-sales value in the forecast and form the H1 sample; the remaining 28 have no matched forecast and therefore no rent measure. Of the 71, 31 also have an LOE expiry date that leaves six forecast years inside the

2025–2046 window and form the H2 sample; the remaining 40 lack either an LOE expiry date or a complete six-year post-expiry forecast.

The forecast provider's methodology is proprietary, and we cannot establish whether, or how, its revenue projections use biosimilar pipeline or competitor-count information. Nor can we confirm that the developers counted in the pipeline correspond to the competitors the forecaster recognises. We therefore interpret H2 throughout as an association between pipeline competition and forecast erosion.

3.2 Variable construction

Entrant count = distinct developers per reference molecule. Rent = originator peak worldwide sales ($m) in the 2025–2046 forecast; we use peak rather than current-year sales as the measure of the rent at stake, because current-year sales understate it for molecules that have already partly eroded. Erosion slope = the annual log-linear growth rate of forecast worldwide sales over the six years from patent expiry (negative = erosion); it is therefore defined only for molecules whose expiry leaves six forecast years inside the 2025–2046 window. Drug class = modal pipeline drug class, collapsed to the six most common classes (TNF-α inhibitors, oncology monoclonal antibodies, insulins, non-TNF-α immune biologics, recombinant blood factors and immune monoclonal antibodies) plus "Other".

3.3 Estimation

Entrant counts are over-dispersed, so H1 uses a negative-binomial count model (with a Poisson comparison and an over-dispersion check):

$$EntrantCount_m = \exp(\beta_0 + \beta_1 \cdot \ln(Rent_m) + \delta_c) \cdot u_m$$

H2 regresses the erosion slope on the entrant count, rent and class fixed effects with heteroskedasticity-robust (HC1) standard errors:

$$ErosionSlope_m = \gamma_0 + \gamma_1 \cdot EntrantCount_m + \gamma_2 \cdot \ln(Rent_m) + \eta_c + \varepsilon_m$$

where m indexes reference molecules, c indexes drug classes, δ_c and η_c are drug-class fixed effects, u_m is the gamma-distributed heterogeneity term of the negative-binomial model and ε_m is the regression error. H1 predicts $\beta_1>0$ and H2 predicts $\gamma_1<0$. We interpret coefficients as features of the forecaster's encoded contestability map; reverse causality (anticipated erosion may itself deter or attract entry) is discussed in Section 3.4.

3.4 Identification and the nature of the estimand

Coefficients describe the forecaster's encoded contestability map, not causal effects. Two threats stand out. Anticipation: forecasters may build steeper erosion where they already expect dense entry, making H2 partly definitional rather than behavioural; we mitigate this by using a mechanical log-linear slope and controlling for rent and class, and in Section 4.3 we check whether the data look as they would if forecasts were set mechanically from developer counts, but we cannot eliminate the threat. Because the

estimand is the forecaster's encoded beliefs, some dependence of forecasts on expected entry is part of what we measure rather than a pure bias. Selection: the molecules with computable erosion slopes are those whose expiry leaves six forecast years inside the window, a non-random subset; we therefore treat H2 as descriptive of forecaster behaviour for near-cliff molecules. The small erosion sample (N = 31) limits power and precludes rich fixed-effect structures, so the magnitude of the crowding–erosion estimate should be interpreted with caution. Reverse causality is a further concern: anticipated erosion may itself deter or attract entry, so developer counts are not exogenous to the forecast, and we do not claim that crowding causes erosion.

4 Results

4.1 Descriptive statistics

Table 1 describes the molecule-level panel. Entrant counts are highly right-skewed: six molecules attract 30 or more developers (bevacizumab, the most contested, has 44, followed by trastuzumab, adalimumab, pegfilgrastim, denosumab and rituximab), while the median molecule attracts three. Erosion slopes are available only for the 31 molecules whose expiry leaves six forecast years inside the forecast window. Pairwise correlations among the main variables are modest: the entrant count correlates 0.13 with ln(peak rent) and − 0.25 with the erosion slope, and ln(peak rent) correlates − 0.37 with the erosion slope. The exception is the clinical-stage entrant count, which correlates 0.99 with the total entrant count.

Table 1
Descriptive statistics, molecule-level panel. Peak sales and erosion slopes are vendor forecast outputs (Evaluate). N differs by variable: developer counts cover all 99 pipeline molecules, peak sales the 71 matched to the forecast, and erosion slopes the 31 with an LOE expiry date and a complete six-year post-expiry forecast (Section 3.1)

Variable	N	Mean	SD	Min	Median	Max
Distinct developers	99	7.25	9.52	1.00	3.00	44.00
Clinical-stage developers	99	6.19	8.60	0.00	2.00	38.00
Originator peak sales ($m)	71	3730.16	6309.18	10.02	1328.66	33352.46
Erosion slope (annual)	31	−0.17	0.09	−0.40	−0.19	−0.01

4.2 Does contestable rent attract entrants? (H1)

Figure 1 plots distinct developer counts against originator peak sales. The slope is positive but shallow: large-rent molecules do attract more developers, yet several mid-rent molecules (filgrastim, epoetin, pegfilgrastim) attract very large entrant pools, possibly reflecting their comparatively mature manufacturing processes (a mechanism we do not test). In the negative-binomial model (Table 2) the rent elasticity is positive but only marginally significant (β = 0.147, p = 0.076); the conventional Poisson estimate is significant (p = 0.014), but the Poisson dispersion statistic is about 10, so conventional

Poisson standard errors are understated. We therefore report the Poisson estimate for comparison only and base inference on the negative-binomial model. Each doubling of peak rent is associated with about an 11% increase in developer count ($2^{0.147} \approx 1.11$). Because the preferred estimate is significant only at the 10% level, H1 is partially supported. The weak result is nonetheless informative: the 90% confidence interval for the elasticity (0.011 to 0.284) excludes zero, and even the upper bound of the 95% interval (0.310) implies that doubling the rent raises developer counts by at most about 24% ($2^{0.310} \approx 1.24$). Moving from the median molecule's peak sales ($1.3bn) to the largest ($33.4bn) is associated with about 61% more developers. The estimated relationship between peak sales and developer counts is therefore positive but modest, with statistical evidence that is sensitive to the specification. Mean entrant counts also vary widely by drug class: about 16 developers per molecule for TNF-α inhibitors and 15 for oncology monoclonal antibodies, against about 2 for recombinant blood factors and immune monoclonal antibodies. This is consistent with class-specific economics shaping entry alongside rent size.

Table 2
Rent and biosimilar entry (H1). Dependent variable: distinct developers per reference molecule. Negative-binomial generalised linear model (log link) with drug-class fixed effects; Poisson estimates shown for comparison only (Section 5). Class coefficients not reported

Variable	Negative binomial: coef.	SE	z	p	Poisson: coef.	p
ln(peak rent)	0.1475	0.083	1.773	0.076	0.071	0.014
Intercept	0.5865	0.620	0.946	0.344		
Drug-class fixed effects	Yes					
Observations (molecules)	71					
Log-likelihood	−215.00					
Pseudo R^2 (Cox–Snell)	0.269					

4.3 Does crowding steepen erosion? (H2)

Table 3 regresses the forecast erosion slope on the entrant count, rent and class. The entrant-count coefficient is negative and significant at the 5% level (β=−0.003, p = 0.015): each additional developer is associated with a steeper projected post-expiry decline, while rent is not significant conditional on crowding and class, even though rent and erosion are correlated bivariately (r = − 0.37). Figure 2 displays the bivariate crowding–erosion relationship, which is weaker (r = − 0.25) than the conditional estimate. The reported p-values use asymptotic z statistics; with t inference on 23 residual degrees of freedom, the entrant-count p-value rises to about 0.023 and remains significant at the 5% level. The 95% confidence interval for the entrant-count coefficient, using t inference, is − 0.0057 to − 0.0005 and excludes zero.

The effect is economically meaningful. Moving from the median molecule (3 developers) to a heavily contested one (30 developers) implies a slope about 0.08 steeper per year, close to one standard deviation of the erosion slope (0.09). The low adjusted R^2 (0.064) partly reflects the number of class controls relative to the sample size. Conditional on rent and class, the entrant count accounts for about a fifth of the remaining variation in forecast erosion (partial $R^2 \approx 0.20$, from $t = -2.434$ on 23 degrees of freedom).

These magnitudes bear on circularity only partly. On its own, the entrant count accounts for about 6% of the variation in forecast erosion ($r = -0.25$), less than rent (about 14%, $r = -0.37$), and the full model leaves most of the variation unexplained. This shows that forecast erosion is not a simple function of the entrant count. It does not rule out shared assumptions, omitted variables or reverse causality, because the forecaster may draw on information correlated with the pipeline (Section 3.1). H2 is supported as a descriptive association between pipeline competition and forecast erosion, with the caveat that a small sample (N = 31) limits precision.

Table 3

Erosion-slope model (H2). Dependent variable = annual log-linear forecast growth over six years post-expiry (negative = erosion). OLS with HC1 robust standard errors. Drug-class fixed effects include only the classes represented in the erosion sample. The model estimates eight parameters (intercept, entrant count, ln(peak rent) and five class dummies), leaving 23 residual degrees of freedom. z statistics are asymptotic; with t inference (23 df) the entrant-count p-value is 0.023 and its 95% confidence interval is −0.0057 to −0.0005

Variable	Coefficient	SE (HC1)	z	p
Entrant count	−0.0031	0.0013	−2.434	0.015
ln(peak rent)	−0.0108	0.012	−0.926	0.355
Intercept	−0.0367	0.080	−0.456	0.648
Drug-class fixed effects	Yes			
Observations (molecules)	31			
R^2	0.282			
Adjusted R^2	0.064			

4.4 When do entrants arrive? (descriptive)

The second contestable-markets prediction is that entry clusters around the fall of the barrier. We examine it descriptively, using the distribution of biosimilar launch year minus originator patent-expiry year, separately for US and EU launches. Entry is concentrated around the cliff: about 65% of US launches and 68% of EU launches fall within a window from one year before to three years after expiry, and both distributions have a median of about two years after expiry. On average, EU launches occur sooner after expiry than US launches (2.76 versus 3.75 years). This pattern is consistent with entry being

timed to the loss of exclusivity, but because it is descriptive it does not establish why entry is timed this way.

5 Robustness

Table 4 reports the alternative specifications and inference checks. For H1, dropping class fixed effects leaves the rent elasticity at the margin of conventional significance (β = 0.133, p = 0.050). The conventional Poisson estimate (β = 0.071, p = 0.014) is reported for comparison only; given a dispersion statistic of about 10, its standard errors are not reliable and it is not used for inference. Across the specifications, the elasticity is consistently positive and small, which is the substantive H1 finding.

For H2, two checks on the reported estimates point the same way. First, using small-sample t inference instead of asymptotic z inference raises the p-value from 0.015 to about 0.023, and the 95% confidence interval still excludes zero (Section 4.3). Second, dropping class fixed effects and using the clinical-stage count preserves the negative sign (β=−0.002, p = 0.034). Because the clinical-stage and total counts are almost perfectly correlated (r = 0.99), the second check mainly shows that the result does not depend on the class fixed effects; it is not an independent test of the crowding measure.

Table 4
Robustness checks for H1 and H2

Specification	Coefficient	p
H1 negative binomial, ln(rent), with class FE (baseline)	0.147	0.076
H1 Poisson, ln(rent) (comparison only; over-dispersed)	0.071	0.014
H1 negative binomial, ln(rent), no class FE (alternative)	0.133	0.050
H2 OLS, entrant count (baseline)	−0.003	0.015
H2 OLS, entrant count, t inference, 23 df (inference check)	−0.003	0.023
H2 OLS, clinical-stage count, no class FE (alternative)	−0.002	0.034

6 Discussion

6.1 A qualified contestable-markets view of the biologic cliff

The results separate two parts of contestable-markets theory. On the consequence side, the evidence is consistent with the theory: denser entry is associated with steeper forecast erosion of originator value. On the entry side, the fit is weaker: the association between rent and developer counts is positive but modest. Biologic markets are far from the frictionless ideal; high manufacturing and litigation costs, interchangeability frictions and patent thickets are plausible reasons for the weak entry margin, although our data do not measure these frictions directly.

Entry timing fits the theory more closely than entry volume: launches cluster around patent expiry, even though the number of entrants responds only weakly to the size of the rent. The headline pattern offers partial support for the contestable-markets lens. Biologic cliffs appear contestable in their forecast consequences but sticky in their entry.

6.2 Theoretical implications

The study refines the contestability lens for high-barrier biologic markets by separating the entry margin from the erosion margin. On the entry margin, market attractiveness (rent) is only modestly associated with developer counts, so entry cost and feasibility are candidate explanations for future testing. On the erosion margin, the study ports the small-molecule "more entrants → faster erosion" result into the biosimilar setting at the level of forecast revenue, complementing evidence from realised prices (Jofre-Bonet et al., 2025).

6.3 Managerial, strategic and policy implications

For originators, the erosion result suggests that the number of credible entrants is associated with the forecast cliff, so strategies that limit or stagger entry — patent thickets, settlements, or own-biosimilar and next-generation launches — merit attention in valuation. For entrants, the weak rent-elasticity suggests that headline originator sales alone are a poor guide to the competitive intensity a target will face; class-specific factors may also matter. For payers and policymakers seeking savings, the findings caution that an expired patent does not by itself guarantee dense entry; measures that lower biosimilar development and interchangeability barriers may be needed to realise contestability, a proposition future work could test directly.

7 Limitations and Future Research

Rents and erosion are forecast-derived, so the erosion tests describe encoded beliefs, and the forecaster's methodology is not observable; the erosion sample is small and selected on near-term expiry; and reverse causality between anticipated erosion and entry cannot be ruled out. The entry-timing evidence is descriptive only. The findings are therefore associations, not causal estimates.

Natural extensions: validate forecast erosion against realised post-LOE declines as more biologic cliffs resolve; instrument entry with exogenous shifts in manufacturing or litigation cost; refine crowding to credible (clinical-stage, interchangeable) entrants; and connect entrant counts to the de-risking economics of the pipeline to close the loop between development cost and post-cliff contestability.

8 Conclusion

Treating the patent cliff as a contestable market turns attention from prices to the supply of entrants. Across 99 reference molecules (71 with rent data), that supply responds to contestable rent only weakly and also varies by drug class; and, in the 31-molecule erosion sample — a non-random subset of near-cliff molecules — denser pipeline competition is associated with steeper forecast erosion of originator

value. Launches, meanwhile, cluster around patent expiry. These are associations in forecast data, not causal effects on realised revenue. The biologic cliff thus appears contestable in its forecast consequences but sticky in its entry — a portrait that both extends and qualifies the classic contestable-markets account, and that is relevant to how the value of cliff-facing assets is assessed.

Declarations

Competing interests:

The authors declare no competing interests.

Ethics Approval:

Not applicable. The study analyses commercially licensed, asset-level pipeline data and does not involve human participants, animals, patient data, or clinical intervention, and therefore did not require institutional ethics approval.

Clinical trial number

not applicable. This study is a secondary analysis of commercially licensed, asset-level pharmaceutical pipeline, loss-of-exclusivity and sales-forecast data; it is not a clinical trial, did not involve the prospective assignment of human participants to any intervention, and therefore did not require clinical trial registration.

Consent to Participate

/ Consent for Publication: All authors have read and approved the final manuscript and consent to its publication. Consent to participate is not applicable, as the study did not involve human participants or identifiable personal data.

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Author Contribution

Abhijit Kirtunia: Conceptualization, Methodology, Formal analysis, Data curation, Writing – original draft, Writing & Editing. Titas Bhattacharjee: Conceptualization, Supervision, Writing – review. Bhaskar Bhowmick: Conceptualization, Supervision.

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Data Availability Statement:

The data supporting the findings of this study were obtained in part from licensed commercial sources, including S&P Capital IQ and a commercial pharmaceutical pipeline intelligence platform. The licensed raw data cannot be shared publicly or deposited in a repository, as third-party licence terms prohibit redistribution. The derived analytical dataset is available from the corresponding author upon reasonable request, subject to the data providers' licence terms, and can be made available to the editors and reviewers for verification. No new primary data were generated in the course of this study.

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Figures

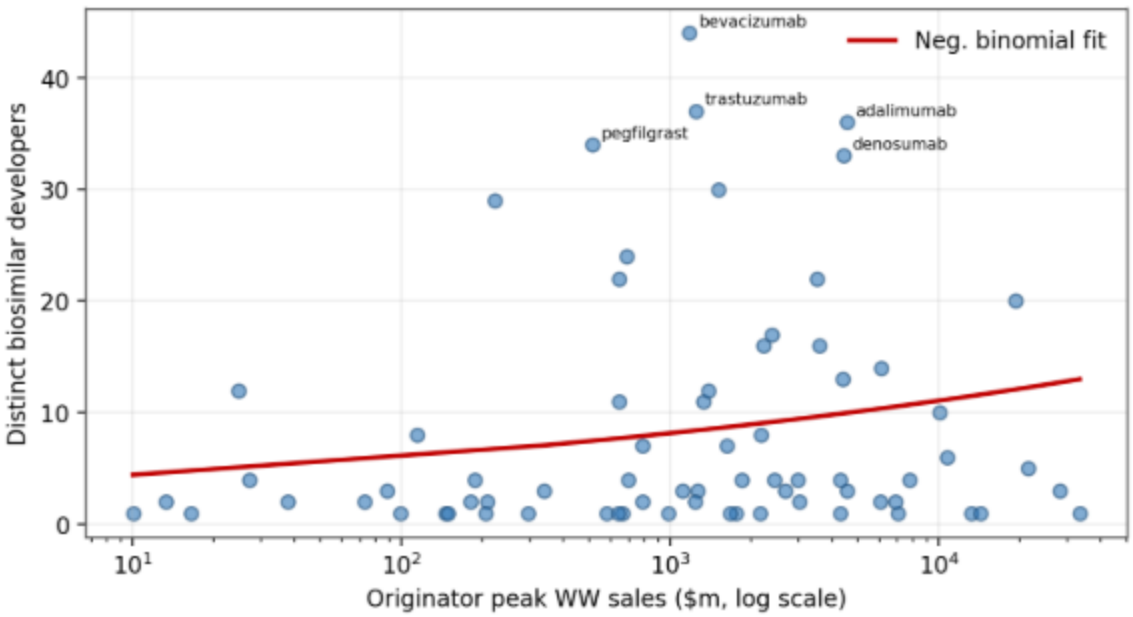

Figure 1

Distinct biosimilar developers versus originator peak worldwide sales, with negative-binomial fit. The plot is descriptive; the estimates in Table 2 also control for drug class

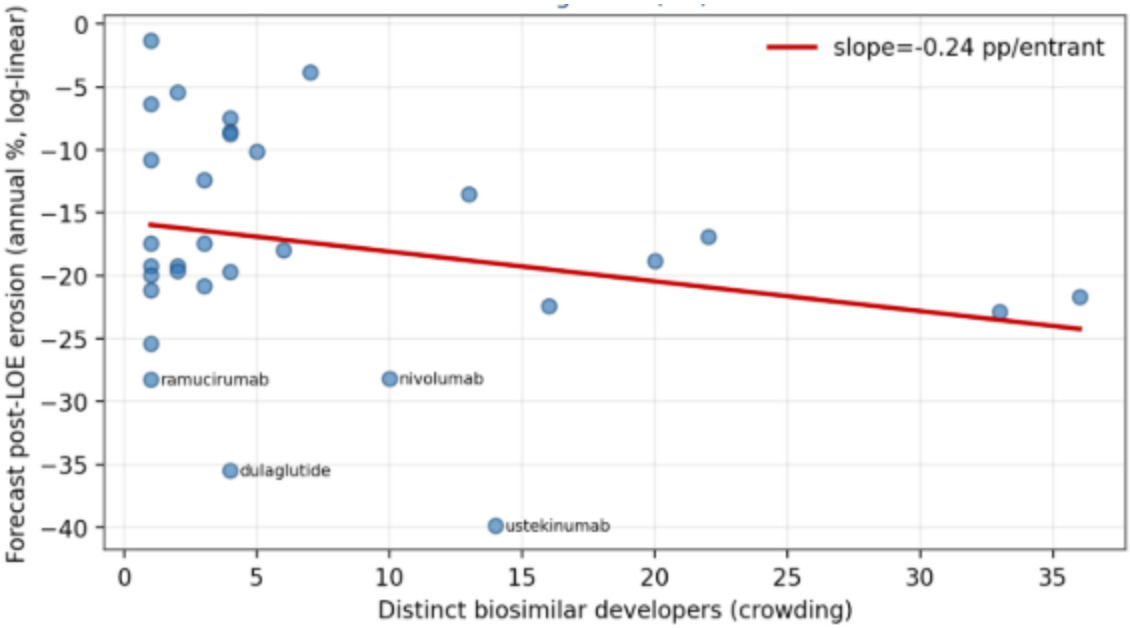

Figure 2

Forecast post-LOE erosion versus developer crowding. The line is a bivariate fit; the conditional estimate is reported in Table 3