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The Determinants of Studies Productiveness in Ethical Drug Discovery

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A B S T R A C T

In 1971, the Pharmaceutical producer's affiliation participants spent approximately $360 million on research and development.l In 1991 they spent $8.nine billion, an increase of over 2300 percent. whilst industry income has grown in step with research expenditures, there has been no full-size increase inside the range of the latest tablets introduced. Why have costs increased so dramatically? Breakthroughs in pharmaceutical research can lay the foundation for qualitative improvements in the quality of existence and big discounts within the price of healthcare, however escalating healthcare fees have centered attention on each factor of healthcare expenditure and feature led several observers to question the apparent decline within the productiveness of pharmaceutical studies. This bankruptcy hopes to contribute to the controversy by exploring the issue inside the context of a broader take look at the determinants of studies productivity inside the discovery of ethical drugs. We draw upon detailed facts set compiled from the internal records of the ten most important pharmaceutical companies. The statistics set permits us to distinguish among studies (or discoveries) and improvement expenses at an enormously dis aggregated stage. as instance, in the standard magnificence of cardiovascular cures, we can observe the distinctions amongst fields together with hypertension, cardio tonic, and blood-associated conditions. This study first presents a few descriptive facts from the sample. Our pattern corporations show a lengthy-term decline in productiveness this is a feature of the industry as a whole. each study and development expenditures have improved dramatically in actual phrases, even as the output of important patents has fallen,2 and the wide variety of capsules observed have remained about regular.

INTRODUCTION

This is an important issue for public policy because it highlights the dangers of relying on the research cost per drug as a useful measure of research costs. On the one hand, if it is significant over investment in research, so that competing firms are racing each other to market by investing in substantially identical research, average search costs per drug per firm substantially overstate the actual expense-denture required to discover a new drug. On the other hand, if there are significant spillovers among firms and research projects within the same firm, and if firms do not immediately dissipate anticipated returns through excess investment, then mean research costs substantially understate the resources required to discover a new drug.

Unfortunately, it is difficult to test those ideas systematically because the theoretical models very quickly become fundamentally indeterminate. As a first step toward a richer understanding of the issue, we focus on exploring the assumptions on which the theoretical literature rests. The rather extreme conclusion that free entry unambiguous only leads to over investment in research are crucially dependent on at least five key assumptions: that entry will occur until marginal private returns have been driven to zero, that there is no spillover of knowledge among firms, that there is total appropriability of consumer surplus, that competing projects are perfect substitutes for each other, and that there are no efficiency gains to multi-firm competition. Testing the validity of the last three assumptions is beyond the scope of this chapter, but we do explore the first by examining the dynamics of investment behavior. Following the methodology pioneered by Scherer (1992){1} and Meron and Caves (1991){2}, we distinguish among a leader, core followers, and fringe firms. We find some weak evidence that core followers invest in response to investment by the leading firm, while fringe firms reduce their investments in research as follower firms increase their research expenditures. Those effects are only marginally significant, however, and of very small magnitude. Our results suggest that by far the most important determinant of one year's research spending is the previous year's spending: a finding consistent with a world in which investment decisions are driven much more by heterogeneous firm capabilities, adjustment costs, and scientific opportunity than by strategic interactions. We interpret our finding as suggesting that while firms may respond strategically to each other, such reactions are probably not sufficiently important to drive marginal private returns to zero.

We then investigate the nature of spillovers in the industry by studying the determinants of the output of important patents. Our results are consistent with the presence of substantial spillovers, both within and across firms, and thus suggest that the entry of additional firms into the R&D race does not unequivocally destroy welfare. The final section of this chapter presents our conclusions and explores their implication for formulating public policy. Our results suggest that the apparent decline in the pharmaceutical industry's long-term productivity is probably a function of the escalating real costs of research. There is no evidence of a shift from easier to more difficult classes, or of an increase in racing behavior across firms. Our research does, however, highlight

the complexity of pharmaceutical research. In the absence of good measures of the returns to innovation in the industry, we cannot know whether firms, on average, make excessive expenditures on R&D. Our results do, however, suggest that while the pharmaceutical industry is sometimes held up as a textbook example of dissipative racing behavior in R&D competition, the reality is probably considerably more complex. In some cases, we find evidence consistent with the kinds of correlated patterns of investment at the research program level that we would expect to see if R&D spending decisions were dominated by strategic interaction of the kind captured by game theoretic models. But we also find evidence consistent with significant R&D project complementarities and other spillover benefits across firms suggest that correlated investment strategies may create significant externalities. While our results must be interpreted with care, they suggest that the simple characterization of the costs of R&D by an average dollar-per-drug figure is almost certainly incorrect.

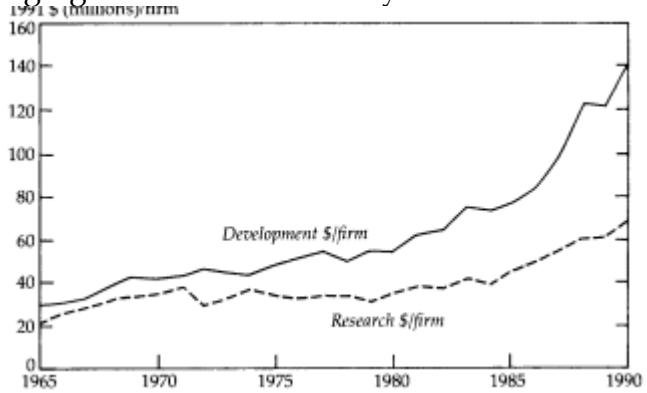

Figure 1. Mean R&D Spending Per Firm

Long-Term Trends in Industry Productivity

Figure 1 plots average spending on R&D by the firms in our sample from 1965 to 1990.3 While research spending has increased in real terms, the lion's share of the increase in pharmaceutical research costs is a function of the accelerating cost of clinical development. Figure 2 plots R&D spending as a share of sales: while research expenditures are increasing roughly in line with sales, development expenditures have far outstripped them. Figure 3 plots the average outputs per dollar from 1965 to 1990. The number of important patents granted to the mean firm in our sample has fallen dramatically. This mirrors trends observed for the economy as a whole, but while the number of patents the Patent and Trademark Office granted to u.s. firms fell in every industry in the 1970s, a number of the firms in our sample are European, and the decline in patenting rates by our sample firms are significantly greater than this more general trend (Griliches 1990).

On average, the number of investigational new drug applications and new drug applications obtained for each dollar invested in R&D by the firms in our sample has steadily declined.s We must interpret that trend with caution because firms can take more than ten years to file a new drug application after the Food and Drug Administration has granted an investigational new drug application. Thus, it is possible that the acceleration in development spending that we observe in the late 1980s will be followed by an outpouring of new drug applications"s

over the next decade. In general, however, our data are in line with the aggregate statistics suggesting that increases in spending on R&D have not been accompanied by a proportionate increase in the easily tracked measures of output: patents, investigational new drug applications, and new drug applications Heterogeneity across Therapeutic Classes Wiggins (1979{{4} first demonstrated the importance of distinguishing among therapeutic classes in modeling the determinants of productivity in the pharmaceutical industry. In Table 1, we begin the process of dis aggregating the data to reveal the heterogeneity of pharmaceutical research.

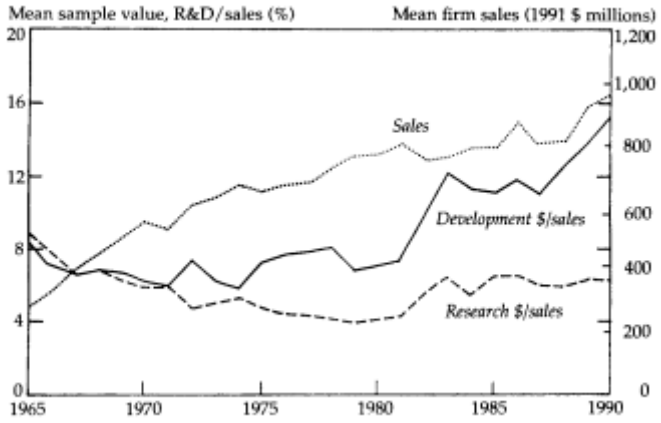

Figure 2. R&D as Share of Sales and Sample Average Sales

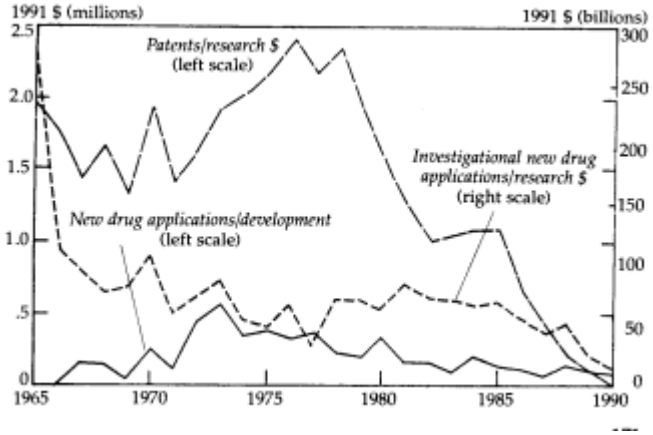

Figure 3. Patents, Investigational New Drug Applications, and New Drug Application Per R&D Dollar

We show the ratio of cumulative outputs to cumulative inputs by therapeutic class for the years 1975 through 1990. We must approach those numbers with caution, because they are subject to both left and right censoring. In the early years, for example, the outputs from each class are partially the result of spending before 1975, and many of the inputs to the process in the second half of the period will not yield results until after 1990. The numbers do, however, illustrate the variation that is hidden by aggregating the data. The number of important patents obtained per million dollars invested in research, for example varies from a high of 2.6 in dermatological drugs to a low of .2 in anti-infective drugs. Similarly, the ratio of investigational new drug applications obtained per billion dollars varies from twenty-five for anti-infective drugs to eighty-one for

dermatological drugs, and the the ratio of new drug applications to cumulative R&D spending varies from a low of six per billion in musculoskeletal research to a high of 34 per billion in dermatology.

Those variations translate into significant differences in the average "cost per drug" in each class. If we assume, for example, that investment in each program is constant across the sixteen years and that the time value of money is 9 percent, they translate into an approximate cost per new drug application of over $370 million for a the musculoskeletal drug, $200 million for a cardiovascular drug, and $66 million for a dermatological drug.

Thus, differences in costs across therapeutic classes are one possible explanation for the apparent decline in the productivity of research n the pharmaceutical industry. If firms have shifted resources away from "easy" fields such as dermatology toward "hard" fields such as anti-infective research, then research costs would rise and output would fall solely as a result of a change in portfolio composition. the mean share of the increases in research costs. In general, firms have shifted investment in research from anti-infective drugs to cardiovascular drugs. The results reported in Table 8-1 suggest that this shift should have increased research productivity when all other things are equal. In development, the firms in our sample have been shifting from central nervous system drugs to cardiovascular drugs, while the share of resources devoted to anti-infective drugs has remained more or less constant. Again, the summary statistics of Table 8-1 suggest that this shift should have left research productivity approximately unchanged, all other things equal.

Thus, although research productivity differs systematically across therapeutic classes, there is little evidence to suggest that shifts among classes are at the root of the long-term "decline" in the productivity of pharmaceutical R&D. To gain insight into changes in industry productivity, we next explore the dynamics of investment behavior and differences in firm productivity.of the research portfolio by therapeutic class over time, while the figurine 8-5 plots the mean share of the development portfolio. Both figures suggest that it is very unlikely that shifts in portfolio composition drive

The Dynamics of Investment Behavior

Escalating the real costs of research in the pharmaceutical industry may reflect increasing competition and "over investment" in research. The theoretical literature exploring the relationship between competitive dynamics and investment strategy is both voluminous and inconclusive, but many of the models raise the concern that free entry into R&D competition will result in over investment relative to both the prilately and the socially optimal investment levels. Intuitively, those results are driven by the assumption that in deciding to invest in research, firms consider only their marginal returns and do not take into account the externality that they impose on other firms in reducing their chances of success. In the extreme, those models suggest that entry will occur until all expected profits are dissipated (Dasgupta and Stiglitz 1980; Loury 1979; Reinganum 1982, 1989){5,6,7,8} Unfortunately, it is difficult to test those ideas. Models that attempt to incorporate all the relevant variables quickly become dauntingly complex, and we have, as yet, no general results about the

relationship among market structure, scientific or technological regime, and the realized and optimal levels of research investment (Harris and Vickers 1987; Reinganum 1989){9}.

The literature does, however, highlight several factors that determine whether the entry of an additional firm into the research race will raise or lower social welfare. For example, one can show that in markets characterized by perfectly competitive behavior, complete appropriability, and research projects that are perfect substitutes for each other, there might be giant over investment in studies (Dasgupta and Stiglitz 1980). Conversely, in industries characterized by weak appropriability, wherein funding in studies is greater cooperative than competitive and in which studies tasks are in large part complements, there's probable to be under investment relative to the social best (Dasgupta and Maskin 1987; D' Aspremont and Jacquemin 1988, 1990; Fraja 1993; Suzumura 1992){10,11,12,13,14} due to the fact theoretical models that try to capture simultaneously the interaction amongst all of those elements fast comes to be intractable, we rather discover the validity of the core assumptions on which the models of hire dissipation depend on first, under loose entry companies will respond strategically to every difference and could invest in search till marginal returns fall to zero, and 2d, that there are no spillovers of information either across initiatives inside the company or amongst corporations. A greater entire dialogue of the theoretical troubles involved and the relationship between our studies and the prevailing literature is given in our have a look at "Racing to make investments?: The Dynamics of Opposition in moral Drug Discovery" (Cockburn and Henderson 1995){15}.

As well known, the literature shows that two workable styles of investment conduct are steady with dissipating conduct. On the one hand, Reinganum (1982) offers a model in which symmetric oligopolistic corporations race for a well-defined prize. below those situations, companies' reaction functions slope upward, and one company's marginal increases in spending are met by way of will increase in its opponents' spending. On the other hand, Harris and Vickers (1987) broaden a model of contention among asymmetric firms in which expanded spending via the leader inspires a submissive reaction using the fans.

The difference between the 2 behaviors builds on in advance work by way of Scherer (1967){16} and is confirmed through previous empirical work. Grabowski and Baxter (1973),{17} for instance, observed that in the chemical industry, the 2 biggest companies answered quickly to adjustments in every different's Meron and Caves (1991) observed that in a sample of twenty8 U.S. production industries, leaders and followers reacted positively to every different's increases in R&D fees, at the same time as a fringe corporations' investment decreased with their larger rivals' funding. Scherer (1992) discovered that firms with extra domestic income in more concentrated U.S. markets were likely to react tons extra aggressively to increase import competition than smaller firms or companies in less focused markets. In tables 8-2, 8-3, and 8.4 we gift our evaluation of the make investments dynamics that symbolize our pattern. desk 8-2 contains the results from regressing investment onto control variables

suggested by the qualitative analysis. They include the stock of research, which is intended to capture, among other things, unobserved differences in the quality of the program; firm and therapeutic class dummies; a time trend; and variables intended to capture shocks to scientific opportunity-"news" in their own patents and important papers. We define news as the excess of the current year's flow over the amount necessary to maintain the stock, given a depreciation rate B:

This formulation is intended to capture activity over normal levels.7 Of all the control variables, only news in patents is significant. We use three specifications for the dependent variable. In model
(1) the dependent variable is just the level of research spending, and
the explanatory variables include lagged research to capture the adjustment costs. This variable dominates the regression, and its coefficient is indistinguishable from one. In model
(2) we constrain it to be one by using the first difference of R as the dependent variable. We include a lagged difference of R in this specification, but it is insignificant. Model
(3) uses a new version of R and lagged news on the right-hand side. Lagged news is strongly significant, which suggests that changes in research strategies are correlated from year to year.

In Table 8-3, we introduce competitors' expenditures into the regression to test for the presence of strategic interactions.8 We reproduce model (3) from Table 8-2 for purposes of comparison. Model (4) tests the hypothesis that every firm responds to every other firm by including news in competitors' research as an independent variable. It is insignificant. Model (5) tests the hypotheses that the leading firm responds only to core followers, while core followers respond both to each other and to the leading firm, and fringe firms respond both to the leader and the core followers.9 All the coefficients except that of the leader's response to the core followers have the expected sign, but only one is significant: fringe firms appear to react submissively to investment by core followers. Moreover, the standard test for the significance of additional variables cannot reject the hypothesis that competitive spending adds no additional explanatory power to either model (4) or model (5). While we must temper our interpretation of this result because our firms together comprise only about 28 percent of the industry, the result provides only very limited support for the presence of strategic interactions among firms.

In Table 8-4, we test for the idea that racing behavior may have increased over time, even if it is not significantly present in the sample as a whole. Model (6) is run using the data from 1961 to 1974, while model (7) tests for the significance of competitive investment from 1975 to 1988.10 Competitive investment is insignificant in both specifications, and a Chow test cannot reject the hypothesis that there is no difference in the dynamics of the two periods.

Thus, we find only very limited evidence of strategic interaction in investment behavior. Moreover, the magnitude of those reactions is very small: together, in the most successful specification, they add only .1 percent to the explanatory power of the regression, and our results suggest that the overwhelmingly most important determinant of a period's investment is the

preceding period's investment. Those results are consistent with our qualitative findings. Highly trained personnel are expensive to hire and to let go of, and dramatic increases in the size of a program are unlikely to lead to equally dramatic increases in its productivity.l1 Discovery research is a highly uncertain process, and our quantitative finding that investments are highly serially correlated is consistent with a world in which investment decisions are driven by heterogeneous firm capabilities, adjustment costs, and the evolution of scientific opportunity.

Spillovers and Research Productivity

In an industry characterized by straightforward duplicative racing behavior, one firm's success is anther's loss since each firm invests in identical research programs and there are no spillovers of knowledge across firms. If there are, however, significant spillovers of knowledge across firms, research productivity may be correlated with competitive investment and additional entry into the R&D race may enhance welfare.

We test for the presence of spillovers in our data by regressing important patents onto a variety of control variables and a set of measures designed to capture competitive activity in the field. We can usefully think of those equations as a production function for important patents in which competitors' research successes enter as inputs to each other's R&D.

Table 8-5 sets out our results. Models (9) and (0) use our full sample. Model (9) suggests that own output and the success of rival firms' efforts are positively and strongly significantly correlated. Using competitors' discovery spending in place of their patents gives very similar results: competitors' investment has a positive and significant impact on their research productivity.12 The model fails, however, to control for changes in scientific opportunity and thus raises the possibility that the observed correlations across firms merely reflect exogenous shifts in opportunity that make it easier to obtain patents in any given class. Model (10) includes key papers as a measure of scientific opportunity. There is no significant correlation between those measures and own output, and important competitive patents remain a significant predictor of own patents Models (11) and (12) repeat those analyses using cardiovascular data alone; model (12) uses the more detailed measures of scientific opportunity.14 Patent output is not significantly correlated with key papers in the public sector, which suggests that major shifts in the stock of public knowledge are not immediately translated into patents. Patent output is, however, significantly correlated with the flow of key papers published by researchers in the private sector. Nonetheless, controlling for that effect strengthens the correlation between own research productivity and competitors' output.

Thus, our results are consistent with the idea that there are significant spillovers of knowledge across firms. Important patents per discovery dollar is likely to be significantly higher if competitors have recently obtained several important patents in the area, and far from leading to a "mining out" of opportunities, competitors' research appears to be a complementary activity to own R&D. Thus, the entry of additional firms into a therapeutic area may enhance welfare. We must qualify that result by observing that not all patents are

equally important. If, for example, a major discovery in an area makes it easier to obtain patents in the area, and if our measures of scientific opportunity do not capture that effect, then correlation in output across firms may reflect no more than the generation of "me-too" patents for "me-too" drugs. Two factors moderate this problem. The first is that so-called me-too drugs may offer important additional therapeutic benefits such as reductions in side effects or improved efficacy with different segments of the population. The second is our finding that output is positively associated with a competitive investment as well as with competitive output, which suggests that we are capturing the effect of genuine spillovers of knowledge.

RESEARCH METHODOLOGY

The research methodology section describes the approach taken to conduct the study. It outlines the research design, data collection methods, and sample selection criteria. The primary data collection involved surveys and interviews with researchers, industry experts, and key stakeholders in the ethical drug discovery field. The collected data were then analyzed using statistical techniques, such as regression analysis and correlation analysis, to identify the determinants of studies' productivity.

RESULTS

The results section presents the findings obtained from the data analysis. It highlights the significant determinants that influence studies productivity in ethical drug discovery. The results may include statistical values, such as regression coefficients, p-values, and effect sizes, to quantify the impact of each determinant. The section may also include visual representations, such as graphs or tables, to enhance the presentation of the results.

DISCUSSION

The discussion section interprets and explains the results in the context of the research objectives. It delves into the implications of the identified determinants on studies' productivity in ethical drug discovery. The discussion may explore the relationships between different determinants and their combined impact on productivity. It also considers potential limitations of the study and suggests areas for future research

CONCLUSIONS AND SUGGESTION

Over the past twenty years, the pharmaceutical industry appears to have suffered a dramatic decline in productivity. We have used dis aggregated data at the research program level to explore that decline in the context of the drivers of productivity in drug discovery. Our results suggest that the decline is probably not a function either of a shift to research in more difficult areas or of an increase in racing behavior in the industry. Rather, our results are consistent with the hypothesis that rising real costs of research in the industry reflect decreasing returns.

The switch to more science-intensive methods of drug research appears to be a major contributor to increasing costs, but the most important driver of cost escalation appears to be the rocketing costs of developing clinical drugs. We speculate that this probably reflects both a shift to the treatment of conditions that require more complex clinical trials and increasing regulatory stringency, but we have no data about those issues.15 In general, our results must be interpreted with caution. Our analysis of investment behavior and spillover effects applies only to competition in research or drug discovery: we plan to explore the determinants of productivity in development in later work. Moreover, the validity of our spillover analysis is crucially dependent on our use of important patents as a measure of output. We plan to extend our analysis by using alternative measures of output. We also hope to enrich our understanding of how the dynamics of the industry have evolved.

Those results have potentially important implications for public policy. Most importantly, they suggest that the presence of several competitors in any given area may increase social welfare. While it may be tempting to think that one could rationalize the amount of R&D conducted by the industry or set prices based on the research expenditures of a single firm, our analysis suggests that it may be dangerous to think of research costs in terms of some measure of "dollars per drug" deduced from the spending of any single firm. A reduction in the number of firms conducting research in any given area may have significant negative externalities, if R&D spending complements rather than substitutes for rivals' investment. Intuitively, the true cost of a the drug may include the costs of those programs in rival firms that failed but that contributed to the industry's common pool of knowledge by spilling information across the boundaries of the firm.

Sample Size and Generalizability: The study's findings may be limited by the sample size and the specific context in which data was collected. To improve generalizability, future research could include a larger and more diverse sample of drug discovery researchers from various organizations and geographic locations.

Subjectivity in Data Collection: The qualitative data collected through interviews may be subject to individual biases and perspectives. To mitigate this limitation, future studies could consider employing multiple interviewers and conducting member checking to enhance the credibility and reliability of the qualitative findings.

Longitudinal Studies: This study provides a snapshot of the determinants of productivity in ethical drug discovery. Conducting longitudinal studies over an extended period could offer insights into how these determinants evolve and their long-term impact on research productivity.

Cross-disciplinary Analysis: While this study acknowledges the importance of interdisciplinary collaboration, further investigation could delve deeper into the specific mechanisms and approaches that maximize productivity in different interdisciplinary settings. Comparisons between single-discipline and cross-disciplinary teams could also be explored.

Metrics for Productivity: The study primarily relies on productivity metrics as a measure of research output. However, productivity alone may not capture the full impact and quality of drug discovery research. Future investigations could incorporate additional measures, such as clinical success rates, patent filings, and citation counts, to provide a more comprehensive understanding of research productivity.

Comparative Analysis: A comparative analysis between different research organizations, academic institutions, and industry settings could shed light on the factors that differentiate highly productive drug discovery programs from less productive ones. Examining best practices and success stories could provide valuable insights and inform strategies to enhance productivity across the field.

External Factors: The study focuses primarily on internal determinants of productivity in ethical drug discovery. Future research could consider the influence of external factors, such as regulatory frameworks, market dynamics, and public funding policies, on research productivity. Understanding these external influences can help identify additional areas for improvement.

Cost-effectiveness Analysis: Investigating the cost-effectiveness of different research strategies and practices could provide insights into how resources can be allocated more efficiently to maximize productivity in ethical drug discovery. This analysis could consider factors such as research investment, failure rates, and time-to-market for new drugs.

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