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Innovation Market Theory and Practice: An Analysis and Proposal for Reform

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Encouraging and/or preserving innovation in mergers and acquisitions have been critical factors in modern antitrust analysis. These aims have been justification for the breakup of proposed research programs targeting diseases as serious as HIV/AIDS and cancer. The rationale given is always to protect competition and enhance the benefits to consumers.

Lawyers and economists justify intervention in mergers based on predictions of what will or might happen many years down the road in scientific research programs. They base those predictions on various theories and assumptions of how companies behave. But an examination of the actual drivers in the research-based pharmaceutical industry, such as the time factor of revenue destruction and the resulting continuing need for new products, along with a review of what happened in key cases after the agencies acted, reveals that those underlying assumptions may well have been unfounded.

This factual consideration of how business actually behaves has been missing from the analysis. This article looks at the leading approaches to “innovation markets.” It then reviews the key cases in which the theory has been applied, and looks to see what actually happened after the case files were closed. In other words, did the intervention do any good, and/or did the lack of intervention do any harm?

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The results of that inquiry strongly suggest that not only was the intervention not beneficial, it may have dampened innovation by reducing the potential reward while ignoring the risks that any innovator is being asked to run.

Innovation market theory arose out of a concern that mergers were reducing innovative capacity. The regular tools of analysis failed to provide a remedy for this sort of highly speculative harm, so the agencies stretched the concept of innovation markets to allow them to act under it. However, the analysis here shows that the perceived risk was based on a misapprehension about how companies actually behave and the nature of innovation itself. Once that is understood, the need to stretch the concept of innovation markets goes away.

This article also proposes an alternative approach, grounded in traditional antitrust but based on market reality rather than theory. When this approach is applied to the facts of the cases, it allows intervention when needed while avoiding speculative interference with scientific and business pursuits.

I. Setting the Stage

The concept of preserving competition in what have been classified as “innovation markets” has been remarkably resilient. It has been the justification for the breakup of proposed research programs targeting diseases as serious as HIV/AIDS and cancer. The rationale given is always to protect competition and enhance the benefits to consumers. But as U.S. Federal Trade Commissioner (“FTC”) Tom Rosch noted, arguing over whether the parties to a merger have market power in an innovation market is a bit like trying to fit a square peg into a round hole. Those markets just can’t be pinned down under traditional antitrust concepts.¹

When one digs a bit below the surface of the innovation market concept, it becomes more and more difficult to figure out whether the application of that concept in an antitrust case has led to good results or bad ones. The actual basis for defining an innovation market in a given case is almost impossible to pin

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down. As will be discussed further below, what we are seeing is often a future goods analysis, divorced from its normal limits in terms of timing and likelihood of market entrance and being extended beyond its limits by cloaking it in innovation market language.

What has been missing from the analysis is a consideration of how business actually behaves, which I believe should be the starting point in any decision whether to intervene in a transaction. This article will look at the leading approaches to innovation markets, dissect what they mean, and look at what they intend to accomplish. It will then revisit the key cases in which the theory has been applied (nearly all of which involve pharmaceutical research and development) to see what actually happened after the case files were closed. In other words, did the intervention do any good, and/or did the lack of intervention do any harm?²

Lawyers and economists now second guess scientists and business people in terms of predicting what will or might happen many years down the road in scientific research programs. But while various theories and assumptions tell how companies should behave and are used to construct rationales for intervention, an examination of the actual drivers in the research-based pharmaceutical industry demonstrates that many of those assumptions are not correct. And to the extent that those assumptions are what underlie the intervention, then the intervention is unsupported.

In these unsupported cases, intervention can seldom be shown to have increased or preserved innovation in the sense of leading to more or quicker products to market. Indeed, results after the cases have been resolved raise serious questions whether such intervention dampened innovation by reducing

potential rewards while ignoring the risks that any innovator must run to be a successful market participant.

This article proposes an alternative approach, grounded in traditional antitrust but based on market reality rather than theory. Just as the end point of innovation is a tangible outcome, the definition of innovation markets needs to be tied to something tangible as well. The 1995 Intellectual Property Guidelines (the “IP Guidelines”) made a strong connection between innovation and something that can be grasped, owned, or measured. It limited innovation market inquiries to cases where the parties have unique access to necessary **tangible** assets and where the capability to engage in the relevant research and development (“R&D”) can be associated with specialized assets or characteristics of specific firms.³ Reviewing the approaches that came after those Guidelines, and measuring them against what actually has taken place and how business actually behaves, leads to the conclusion that this modest definition from 1995 provides the best real world anchor for the theory, allowing intervention when needed while minimizing purely speculative interference with scientific and business pursuits.

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II. The Prehistory of Innovation Market Theory

In its most obvious meaning, an innovation market would mean a market for innovation itself, suggesting the auctioning off of a team of expert scientists who are the only ones in their field producing the result that if one bidder wins, everyone else loses. That clearly is not factually accurate. Any workable theory needs to come up with a more useful and practical approach.⁴ And no matter how creative agencies may want to get, at the end of the day any analysis of markets is tethered to statutes and regulations, Section 7 of the Clayton Act in the United States, and Article 101 of the TEUF (and the Merger Control Regulation in the European Union). Unless the defined innovation market is at least consistent with the statutes and precedents, it is not much more than an interesting academic exercise.

Perhaps the most striking characteristic of the early cases cited for the development of innovation markets is that those cases, on their facts, did not need to speak of “innovation markets” at all. The concept was thrown in, but neither the facts nor the holdings required it.

For example, *Smog Control Devices (1969)*⁵ was an alleged agreement among car manufacturers to slow down development of pollution control devices and make sure that no one car maker got ahead of another. As a horizontal agreement not to compete in a field, no new kind of analysis was required to condemn it.

U.S v. GM (1993)⁶ involved certain truck transmission production facilities that were characterized as a specialized asset. The innovation market consisted of the two companies with distinctive assets in place to do R&D, manufacturing, and sales in a limited and defined product market with high entry barriers. While the Department of Justice (“DOJ”) tried to claim that the case was about a broader innovation market,⁷ on the facts of the case there was no need for any kind of new theory.

Rereading some of the material from 1990-2000, one comes away with the strong sense of *déjà vu*; that the enforcement agencies were trying to create a broader rule by adding language to cases where no broader reach was required by the facts, and then talking about the broader rule as if it was established law.⁸

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The next major development in innovation market analysis came with the publication by the DOJ and the FTC of the IP Guidelines in 1995. In discussing the markets that could be affected by licensing arrangements, the Guidelines broke down the universe into three types of markets: (1) Goods; (2) Technology (licensing); and (3) Innovation/R&D.⁹

The IP Guidelines recognized that Innovation or R&D presented different issues than markets made up of goods or technology, and that an unchecked definition of innovation markets could lead to unguided intervention. Indeed, this is what seems to have taken place in some cases. Why this is so, and what it has meant for innovation in the real world, will be discussed below.

III. Why Is Innovation Important?

Before analyzing how to best define innovation, it would be good to explore why that question is important. Start with classic paradigm of the white-coated person in a lab. Why are his actions of importance to anyone else?

First, of course, it can be good to extend the thresholds of knowledge for its own sake. Also, smart people like/need to have time to just explore areas in order to keep their minds sharp for more commercially dedicated disputes.

But the main reason that people care about research or innovation is because it can lead to new or improved products (and processes) in the future.¹⁰ This may result in making existing products better and/or less expensive for consumers, or the development of new products, such as more efficient power sources, cleaner air, or new medicines to treat diseases. And this leads us to a point that tends to get overlooked in the debate. R&D has value, in large part, because the end point has value. And that end point can almost always be measured in a product market.

FTC Commissioner Rosch focuses on exactly this point, when he defines the key question when analyzing innovative market actions as “[W]hether from a policy standpoint, the application of antitrust laws to innovation markets provides consumers with better products or products that are developed more quickly.”¹¹

So the question becomes how the DOJ or the FTC can predict today, when the decision whether to intervene in a transaction has to be made, what will be the results of given R&D—if and when it leads to any results at all. This often is a very fact dependent analysis. Society may well be better off in some cases having two or three projects in the hands of one company rather than in three separate companies (where that one company has the scientists, the money, and the infrastructure to bring the research to fruition as one or more products, whereas other companies are too small/thinly funded/scientifically light to advance the projects).¹² This is not to say that this is always the case. It certainly does appear that the question is fact dependent.¹³

But before an attempt can be made to analyze any particular real world fact situation, there are a couple more awkward questions for any innovation markets theory or theorist:

1. How can one determine how much R&D is good, or better?
2. Can someone monopolize the R&D that has been so identified and, if so, how?

IV. How Does One Measure, Acquire, or Monopolize Research and Development?

How does one measure innovation? Make it more concrete: how does one determine how much R&D is “enough” or “right” or “too little”? These terms only make sense within a system that allows measurement.¹⁴ So here are some possible measures of R&D:

1. Amount of money spent;¹⁵
2. Number of patents;¹⁶
3. Number of products in development, or launched.¹⁷

None of these seems really satisfactory. What is missing is a measuring rod, and then some kind of boundary condition (to determine what is being measured). If the standard is the number of patents, for example, one needs to ask, “patents for what?” This is really simply another way to revisit the matter of defining an innovation market—how can one define it when there is no product yet and perhaps never will be?

So should R&D be measured by number of compounds or products in development? At what stage? To try to measure R&D by spending costs highlights the fact that not all spending is effective. To try to measure R&D by the number of compounds or projects simply encourages odd counting and measuring for the sake of measuring. If a company is studying one compound for three uses, is that one or three in the measuring system?¹⁸

Such a simplistic counting cannot be enough. If one company has five compounds in research for treating bacterial infections, and another company has five compounds in research for treating high blood pressure, this says very little about what a merger would do. Putting the projects together would not seem to lessen any work in either field. And even if an enforcer could do something with the numbers internal to the merging parties, it would still need to know who else is capable of and/or is doing work in either field before that enforcer could figure out what the numbers meant.

The theoretical analysis keeps crashing on one basic rock—to monopolize or to reduce competition, there has to be a defined market.¹⁹ Effects do not take place in the ether.²⁰ So let's take a different tack for a moment.

Is the concern about a reduction in the number of projects in a field, or really about a reduction in the independent innovative capacity in that field? If the answer is “the number of projects,” then you need to explain how you determine an optimal number of such projects. That is heavily dependent on the facts of each case. More projects may be better than fewer, but more projects also may be worse (three weak candidates may not be better than one strong one).

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So what about independent innovative capacity—could someone monopolize it, and what would that mean?²¹ While patented technology can be monopolized, the components of modern R&D (scientists, laboratories, computer access) are available worldwide.

This view makes it inherently difficult to imagine anyone monopolizing R&D in any sense or in any field. Perhaps for this reason the 1995 IP Guidelines came at the issue from the flank. They limited innovation market inquiries to cases where the parties have unique access to necessary **tangible** assets; where the capability to engage in the relevant R&D can be associated with specialized assets or characteristics of specific firms.²²

This approach clearly would work in the Smog and the truck transmission cases. But what constitutes a “specific asset” isn't always obvious. Back in 1995 Richard Rapp raised the concern that the agencies would simply ignore the

“specialized assets” requirement,²³ and the cases that have followed suggest that may have been exactly what has happened.

Most innovation market cases are in the pharmaceutical field, and almost all are settled by consent order. A company may agree to a divestiture because the alternative is significant delay in getting the deal done. And given the odds against success for any given project, a fight to death to save one R&D project may well not be worth having.²⁴ But the fact that the merging parties may have given up on an issue does not mean that intervention was justified, correct, or helpful.

V. Why Should Society Worry about Research and Development Projects, and What Should the Goal Be?

Society cares about research and development, in fact in innovation in general, because it can lead to new or improved products (and processes) in the future. These improvements may result in making existing products less expensive for consumers or the development of new products—whether that means more efficient power sources, cleaner air, or new medicines to treat diseases. R&D has value, in large part, because the end point has value. And that end point can almost always be measured in a product market. In other words, I am looking to regulate the inputs based on a hypothetical impact on the outputs.

Acquiring research and development or innovative capacity is clearly different from acquiring something such as a raw material source. The kind of innovation being discussed here requires access to scientists and other people, so surely whatever it is being spoken of as being “monopolized” cannot be controlled in the same sense that one can monopolize a market for garbage collection by purchasing all of the outstanding permits in a town or city.²⁵ Much of the discussion about innovation and research speaks in terms of what might be under various scenarios. But while these theoretical constructs are often ingenious and sometimes elegant, they often fail when one looks at actual cases and analyze what has happened after either the intervention or non-intervention of the authorities. What needs to be done is to take the argument from “what might be” down to “what is.”

Perhaps the most ambitious recent attempt to grapple with this area is Michael Carrier’s, who deals with potential relationships between market structure and innovation, and constructs an ingenious test based on various theories of innovation suppression and competitive activity.²⁶ There is much

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valuable material in his discussion of pharmaceutical R&D cases, and his frank approach at looking at compounds reasonably likely to make it to market. After analyzing the data, Carrier defines “reasonably likely” for pharmaceutical R&D as Phase III (where the chance of success is over 50 percent and the timing is 2-4 years).²⁷ This is the same standard routinely used by the European Commission in such cases.²⁸ Phase III compounds are real future goods.

But when the argument moves to discussing theories of whether or why a merging firm might suppress innovation, the analysis unfortunately does not reflect the reality of the current research-based pharmaceutical industry.

VI. The Reality of the Research-Based Pharmaceutical Industry

The unceasing need to generate new products and new revenues, the uncertainties of R&D, and the FDA’s approval process and timing all strongly argue against any assumption that a company would try to retard innovation by acquiring a company and then suppress its R&D. One counter hypothetical is often given, but it actually supports the point. In the situation where one company has a dominant product on the market and the other company has the late stage compound most likely to disrupt the market during the patent life of the existing product, a classical “actual goods”/“future goods” analysis counsels one to look closely at the transaction. But this is not an innovation market scenario and does not impact innovation *per se*.

The critical point for the research-based pharmaceutical industry that often is overlooked is patent life. Any monopoly that may result from patent protection has a defined life and a defined end point. This life span needs to be a key part of any analysis of what parties are likely to do.

This industry depends on patents to an extraordinary extent.²⁹ And in the drug field, patents provide a shorter effective life than in almost any other field as a result of the long testing process that has to take place before a patented compound can become a marketed drug product.³⁰ When that realization is combined with the fact that the vast bulk of the expenditures in drug R&D are loaded into Phase III (the large scale clinical tests³¹), and that even there over 40 percent of the compounds fail, you have a context where finding the next successful compound is a never ending hunt.

However, this context had not led to the extinction of “small science” (companies of less than enormous size or what used to be called small- or mid-sized companies). In fact, it has led to an interesting multi-tier structure, with large companies that can and do oversee broad scale clinical testing (the “Development” in R&D), and a large number of smaller companies (some much smaller) that do basic research. Many of these smaller companies are funded by

venture capital firms, which provide money up front hoping to cash out if the science is successful and the company can be sold to a large pharmaceutical company or the product licensed out on good terms.³² In addition, scientific research is done in countless universities, many of which have made substantial sums licensing their results out to pharmaceutical companies. Perhaps the most famous example is the Cohen/Boyer patent on cloning at the University of California at Los Angeles, which earned the university over \$300 million in license fees and royalties.³³

So, to say as Carrier does, that the pharmaceutical industry meets the test for applying innovation market analysis because “the capabilities to engage in the relevant [R&D] can be associated with specialized assets or characteristics of specific firms,”³⁴ is an understandable attempt to create an analytical framework, but ultimately is either tautological (these are the only firms that can do the work because these are the only firms doing the work) or not in accord with reality. Indeed, over time, companies that have worked in one disease area often shift to another. It does not mean that they were incapable of doing work in the second disease area before, only that they chose not to do so.

Assets are always limited, and the allocation of assets (including research spending and direction) is a key function of management. Even a company investing billions of dollars cannot be invested in every potential disease area and scientific approach. However, assets can and have been reallocated. To look at current activity and conclude that everyone not in a certain field must be incapable of working there is to jump to an unsupported conclusion.

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The hunger of big pharmaceutical companies for new drugs is insatiable.³⁵ There are three reasons for this. First, finding, developing, testing, and selling drugs are what drug companies must do to continue to exist. Second, once a company has reached a level of sales, it needs to stay there (or increase it, along with profits) to satisfy its shareholders. Third, products are not static. In the prescription drug universe there is no such thing as having a “natural monopoly” that can continue indefinitely. Once a major drug loses patent protection, generic versions quickly come on the market and drive the price down dramatically.³⁶ Indeed, sometimes a company’s sales can be hurt when someone else’s drug goes generic (and therefore becomes cheaper and the preferred choice of payers such as governments and insurance companies).³⁷

So while economic theory might counsel that a company “should” sit back and milk the “monopoly” cash cow, the realities of the pharmaceutical market place impose a different paradigm. It is the *time factor of revenue destruction* that is often omitted from the analysis, but which, in fact, drives the business decisions.

Consider the following hypothetical case. A company has a major prescription drug product on the market, with seven years left on its key patent. This company sees a compound that is just entering Phase III that shows great promise in that same field and is available for acquisition. Should the operating assumption for the DOJ or FTC be that the company making the acquisition would develop the compound or suppress it?

Based on the market realities discussed above, in almost every case the company will want to develop that new product, for some fairly evident reasons. The company's existing product has a limited financial life, and that time is running. And there may be other products that compete with it that are going off patent sooner, which will add even more pressure on the company's product. Even a Phase III pharmaceutical compound has a 40 plus percent chance (on average)

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of failing. The company needs one or more new products to pick up the slack when the revenue stream from the old one dies.

Not only can a company have more than one drug in a field (i.e. potentially competing products, differentiated in marketing), it likely wants to have another product on the market before the patent expires on its existing one, so that it can move prescribers to its new (patent protected) product. And, of course, based on the failure rates of compounds, a smart company will want to have multiple candidates in the pipe line, in case one crashes late in the game. It is depressingly easy to find examples of such late stage failures.³⁸

If the company buys and suppresses the new compound, when the patent on its existing product expires, the company has nothing. The thought of losing a major revenue stream and having nothing to replace it can, and should, give management nightmares. The idea that a company would buy up potential next generation products in order to kill them off simply does not accord with reality in the research drug industry. In fact, one could reasonably argue that the company already in a market has at least as great an incentive to develop the next generation product (or develop a compound acquired from outside) than does any other company.³⁹

In much of the analysis there seems to be an underlying unexpressed bias that society would be better off if each compound was owned by a separate company. This atomistic model is not supported by any research of which the writer is aware. And it is contradicted by the fact that people working in a field often become better in that field over time. A company working on AIDS drugs is more likely to develop the next drug than a company that has never worked in the area.⁴⁰

VII. Clearing a Path to a New Theory of Innovation Markets

Before one can make a sensible proposal for how to handle innovation markets, it is necessary to set out just what would qualify as such a market under the definition.

A. INNOVATION MARKETS SHOULD BE A LAST RESORT ANALYSIS

Given the problems in defining innovation and determining which conditions help or hinder it, innovation markets should not be the first choice to use a context for analytical approach. If something fits under a more solid and established category, that category should be used.

1. Any subject area in which there is a product already launched should not be treated as an innovation market. It can be treated as an actual goods/future goods market, with which the enforcement agencies have a lot of experience. Recall that the whole point of innovation is to create and produce new products. In the prescription pharmaceutical area, Phase III compounds and/or anything likely to be approved within about 2-3 years should qualify as an initial screen.⁴¹ This future goods/products idea is the general approach taken by the European Commission in the proposed reform of the guidelines for cooperation among rivals.⁴²
2. Where the market consists of IP, this should be analyzed as a property market and not an innovation one. If one company owns a portfolio of patents in a field and the merging partner owns a complementary portfolio, combining them may preclude others from doing research, or at least make it more expensive to do so. But this has nothing to do with the idea of innovation itself. Patents are assets.⁴³ If one company has such assets in a field, and it attempts to acquire more of those assets, the competitive effects of this acquisition can be analyzed using traditional antitrust theory.

These alternative approaches should be applied to many cases formerly classified as innovation market cases. Of those cases that remain (i.e. outside of the actual goods/future goods or IP markets), I will try to see how they can be analyzed in terms of what potential harm would be allowed by the merger, whether that potential harm is likely or plausible under real world conditions (based on what actually happened), and whether such potential harm is likely enough to occur to justify intervening in the transaction.⁴⁴

The analysis starts from the premise that the parties should be allowed to make their bets (after all, a merger is actually a bet that the two companies can operate more efficiently as one than they did as two) without interference from antitrust agencies, unless the agencies can show a real potentially adverse impact on competition.⁴⁵

Also, while it is seductive to think that the peculiarities of pharmaceutical regulation and R&D can mean that the capabilities to engage in the relevant [R&D] can be associated with specialized assets or characteristics of a small number of specific firms,⁴⁶ a quick look at investments by venture capital firms will reveal that there are dozens, if not hundreds, of small inventors in the drug

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industry. There also are countless universities, all eager to partner with companies.⁴⁷ The only specialized characteristic that companies need to have in order to do pharmaceutical research and development is wealth and the willingness to place large bets on scientific candidates that might never become successful products. But by that standard, surely Goldman Sachs qualifies as one of the potential participants, as does Exxon-Mobil.

So with this as prelude, it is time to look at some key cases, and see what remedies were ordered (or why they were not), and what actually happened after Dorothy went back to Kansas and the case files were closed.⁴⁸

B. WHAT THE AGENCIES DID, AND WHAT HAPPENED NEXT

1. 1990—Roche/Genentech⁴⁹

The FTC alleged a market to be “CD4-based therapeutics for the treatment of AIDS and HIV infections.” The allegation was that a limited number of companies were developing CD4 based therapy, and that Roche had patent applications pending on its compound (but not on the field as a whole, so as to preclude anyone from doing work).

Even assuming that isolating a type of attack on a disease is a legitimate way to define a market (the analysis does not pivot on this point), Genentech was in Phase I studies of its compound, and Roche had not even entered the clinic with its compound. A third company, Biogen, was in Phase I/II studies with its compound.⁵⁰ If this is a product market, and the FTC is looking at future goods, these companies are too far away from market production and the odds against success are too great to warrant intervention. Recall that a Phase I compound has only a 10-15 percent chance of reaching the market, and likely will take 8-10 years to do so.⁵¹ A pre-clinical compound is even farther back than that, with an even lower rate of success.

Roche was required to grant non-exclusive patent licenses to its technology. All of the projects later failed.⁵²

Whatever the merits of a product market approach here, an innovation market attack fails at the start. While only a limited number of companies were

developing CD4 based therapies, there was no allegation that there was any practical limit on the number of companies that could undertake such a project. In the terms of the IP Guidelines at 3.2.3 there is no reason to think that “the capabilities to engage in the relevant [R&D] can be associated with specialized assets or characteristics of specific firms.” In fact, this approach to treating AIDS simply was a high-risk proposition approach that most firms chose not to take. And based on the results, those other firms were right. What the FTC did was to take what should have been an analysis based on future goods rules, apply it to compounds that were very far removed from reaching the market, and wrap the analysis up in innovation market language.

By intervening, the FTC, in effect, told the parties that it was reducing the potential rewards from pursuing a risky and expensive research venture (and one targeting a serious health issue—AIDS), in order to make sure that in case the parties did succeed, another party might be able to copy the same approach. That intervention was potentially harmful and, at best, not helpful.

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2. 1995—*American Home Products/American Cyanamid*⁵³

The alleged market was a vaccine to treat rotavirus. No such product existed. The allegation was that the merging companies were two of the three producers with projects either at or near the clinical trial stage of FDA review. In fact, American Home Products (“AHP”) was in Phase II/III studies, and American Cyanamid appeared to be still preclinical.⁵⁴ The FTC required that the American Cyanamid project be licensed out.

In terms of future goods, the American Cyanamid project clearly was too far out to be any sort of a factor. It was at the preclinical phase, which gives it less than a 10 percent chance of success and a time line of likely at least 8-10 years.

One can make a powerful argument that no intervention would have been the best course. If the AHP compound failed, which it eventually did in 1999 based on a side effect (after FDA approval and launch), then AHP could have applied that knowledge to the other project. And if the AHP product succeeded, it was so far ahead of the time line for the Cyanamid compound that there well might have been no market overlap at all. In fact, the Cyanamid compound never reached the U.S. market.⁵⁵ Another company entirely, Merck, launched its own rotavirus vaccine in 2006.

3. 1995—*Glaxo/Wellcome*⁵⁶

The alleged market was a specific chemical approach to treating migraine headaches (using 5HT-1D agonists). Each party was developing an oral form of such a drug. Glaxo had a product on the market in injectable form. Glaxo also had an oral Phase II/III compound. Wellcome had a Phase III compound, likely to be the first to market for the oral form. The FTC required the divestiture of the Wellcome Phase III compound.

If the market is defined as treatment for migraine, or even 5HT-1D agonists for treatment of migraine, then there exists an actual product market with one party as the dominant seller and the other party with a Phase III compound that is the most likely next entrant (future good). There is no need to talk about innovation markets at all on these facts.

But what if one looks at injection as a disfavored method of administration, so that there are no existing products but just two research programs? In fact, although this was not included in the case data, it appears that Glaxo was working on spray and tablet versions of its injectable product, and these were approved by the FDA in 1997.⁵⁷ Glaxo continued to lead the market through at least 2006.⁵⁸

As an actual goods/future goods case, this is straightforward. The remedy would be justified, and there is no reason to get to innovation markets at all.

4. 1997—*Ciba/Sandoz*⁵⁹

The subject was gene therapy products and research. No one had a product on the market, but the merging parties were alleged to control the IP necessary to commercialize products in the field. They were also identified as two out of only a few entities capable of commercially developing such products, but it is unclear if this was a separate allegation towards an innovation market theory or simply a restatement of the IP position. If the companies controlled the key IP, then they could exclude others from the field and therefore, by default, they were among the few (if not the only) ones legally capable of doing work in the field. Various non-exclusive licenses were required to allow the merger to go forward.

As of 2008, there was no gene therapy product on the market. In contrast to the forced divestitures of compounds or R&D projects, the issue here is more clearly viewed as one of an IP market—the market was the IP allowing/preventing others from doing work in the field. Allowing the companies to merge potentially created a patent bar that would not have existed but for the merger. So even if many companies had the scientific ability to do R&D in the field, they would not have been able to because of the IP block. One would have to know what the patents covered, and what was covered by the required licenses, to make a full evaluation.

5. 2000—Pfizer/Warner Lambert⁶⁰

While a number of issues could be raised about this case, the innovation market issue is framed by the FTC's definition of an innovation market consisting of research and development of epidermal growth factor tyrosine kinase inhibitors (referred to as EGFR-TK inhibitors) for the treatment of solid cancerous tumors. There are various ways to treat such tumors. As for the one at issue,

“While the complete mechanism of action is not entirely understood, the drug appears to impede cell-cell signaling pathways which have been implicated in rapid cell division and survival. Over activation of these pathways are thought to be central to tumor growth and metastasis.”⁶¹

This quote is significant because it makes clear that however this compound may work, it is only one of a number of approaches to blocking tumor growth. At the time of the transaction, there was no EGFR-TKi product on the market. AstraZeneca had a Phase III compound, Imclone had a Phase III compound, Pfizer had a Phase II compound (in a partnership with OSI, a small biotech company), and Warner Lambert had a Phase I compound that arguably used a different mechanism of action. So even on this market definition, there were four companies in the market, the merging parties were the farthest behind, and no one suggested any limit on the number of companies that could do work in the field (and might well do so if the concept proved to be effective and safe).

On its face, given that two other companies were more advanced even in the limited field being considered, and that the merging parties were in relatively early stage development, it is hard to see how intervention was justified. The FTC required the divestiture of the Pfizer/OSI compound (the more advanced one), likely because the partner OSI could be relied upon to continue the work with less potential uncertainty as would have existed with an unrelated purchaser of the Phase I compound. Indeed, OSI did more than that. It partnered first with Roche and Genentech for \$187 million⁶² and in 2010 the entire company was sold to Astellis for \$4 billion, in large part on the performance of the compound.⁶³ The compound that Pfizer was allowed to retain never got out of the testing phase.

The end result was three products on the market using the designated pathway: Imclone, OSI, and Amgen (not even on the charts in 2000). AstraZeneca's product was put on the market, but pulled in 2004 for lack of efficacy.⁶⁴

Even on the very narrow market definition, out of two Phase III compounds, one made it to market and stayed; out of two earlier stage compounds, one made

it to market. The facts following the merger are solid: there would have been no harm to competition if no divestiture had been required.

It is worth exploring the language of the Order for what it tells us about the FTC's express analytical process. First, the FTC claimed that Pfizer could delay one compound or drop it, leading to "less product innovation, fewer consumer choices, and higher prices in the marketplace."⁶⁵ Let's parse those phrases for a moment.

IT IS WORTH EXPLORING
THE LANGUAGE OF THE ORDER
FOR WHAT IT TELLS US
ABOUT THE FTC'S EXPRESS
ANALYTICAL PROCESS.

1. *Pfizer could delay or drop one compound.* This is something that can happen in every merger with a potential overlap in research. If this is the test, it proves too much. No transaction would be allowed. Here, given the failure rate of earlier phase compounds and the fact that

two other companies were much farther advanced in the process, it would make no business sense to drop or delay anything. One should not overlook the distinction between what is theoretically possible, and what a party in the real world is likely to do.

2. *If Pfizer dropped one compound, it would lead to fewer consumer choices.* This is a very odd way to describe competition in medical research. The question is what is likely to work best, on which tumors, with which side effects. Two different compounds are very unlikely to act in identical ways. Arguments about consumer choice assume that cancer therapy is like flavors of chewing gum. And it assumes that each research product will lead to an actual product. Again, the theoretical language is broad, but it doesn't connect to the facts on the ground.
3. *If Pfizer dropped one compound it would lead to higher prices in the marketplace.* There is no supporting data for this astounding characterization of the cancer therapy marketplace. Is the FTC saying that the price of the OSI compound would be lower if the Pfizer compound had come out? And is it saying that the earlier stage compounds would have made it to the market?

As a general rule, first generation products tend to price at parity with each other or close to it (depending upon efficacy, toxicity, and the like). A truly superior product might try to command a premium, but reimbursement these days is so complicated that it is unclear whether even a better product can command a higher price.⁶⁶ When a new generation of products comes along, the older one tends to drop in price. But the factors that constrain pricing on patented prescription drugs in general, and cancer therapies in particular, have nothing to do with the classical economic theories of competition. Often, the major question is not "How many products are out there?" but rather "How much will the government and the insurers pay for a drug that extends life by X months?"⁶⁷ The structure of the prescription drug market, especially as more and more decisions are made by governments and insurers based on cost effectiveness grounds,

means that one has to be very careful about general statements about what “would” lead to higher prices.

None of the stated grounds justified the intervention in this case, and the facts of what later took place in terms of drug approvals confirm that no intervention was needed or useful. The proper approach here would have been a future goods analysis. On that basis, no intervention would have taken place.⁶⁸

6. 2001—*Genzyme/Novazyme*⁶⁹

This is the poster child for pure innovation market analysis. As described in the FTC Press Release:

“Pompe disease is a rare, often fatal, disease affecting infants and children, for which there is currently no effective treatment. Because of the relatively limited number of Pompe patients, therapies for Pompe disease fall under the Orphan Drug Act (ODA). The first Pompe therapy to gain FDA approval will obtain seven years of market exclusivity under the ODA. A second therapy may break that exclusivity only by establishing superiority over the first therapy.”⁷⁰

What is interesting is the debate between Chairman Muris and Commissioner Thompson over the decision to close (in 2004) the investigation of the merger which took place in 2001.

The opening salvo was whether indeed increased concentration leads to decreased innovation. Muris cited work showing that such a link has not been established. This is not surprising, since innovation is not a unitary concept. What encourages innovation in the attempt to find a cure for cancer may well not be the same thing that encourages innovation in the ways to decrease energy use.

Here, only two companies were working in the field. Given that the disease at issue affects a small number of people (i.e. the potential market for any end product is small), and that the research was at the time preliminary, risky, and expensive, it was not likely to draw others to participate in it. And this leads us to the most important part of the Muris opinion—his deep dive into the facts of the case.

At the time of the cases, and the opinions being discussed, there was no treatment for Pompe disease.⁷¹ The issue for Muris was whether the merger was likely to reduce the incentive to invest in the R&D on Pompe disease and whether it was likely to give the merged firm the ability to conduct that R&D more suc-

cessfully.⁷² The question is not, and cannot rationally be, whether gross R&D spending will be reduced. Almost every acquisition or merger does that; it is part of the efficiencies that companies look for when doing a deal. Even where the projects directly overlap, combining them can lead to administrative savings. And this does not even reach the difficult and fascinating question of how to deal with a reallocation of assets—a decrease in R&D for one disease or approach vs. an increase for another. Is this good or bad for innovation, and how would you know? On the facts here, two R&D programs had already failed because they could not produce the enzyme on commercial scale. Genzyme and Novazyme had the remaining two programs.

Genzyme was a significant biotech company, with over 5,000 employees in 2001 and revenues approaching \$1 billion. Novazyme was a relative start up, with no sales and some 80 employees. At the time of the merger, the Novazyme project was in the early pre-clinical stage. Genzyme had tried two joint ventures in the field, and both had failed. As a result, and using the knowledge from those failures, Genzyme was ramping up its own project. At the time of the merger, its compound was also at the early pre-clinical stage.

“SOMETHING WAS DELAYED, THEREFORE YOU INTENDED TO DELAY IT” IS A CLOSE COUSIN TO “ONLY TWO PEOPLE ARE DOING RESEARCH IN THIS FIELD THEREFORE ONLY TWO PEOPLE ARE CAPABLE OF DOING RESEARCH IN THIS FIELD.” THE EXTRAPOLATION FROM OBSERVATION TO CONCLUSION IS UNSUPPORTED.

It bears noting again that for drugs entered in Phase I testing, the failure rate is between about 75-85 percent.⁷³ These compounds were even farther back. It was by no means likely that either of these projects would make it to the finished drug stage.

Muris then looked at the impact of the Orphan Drug Act. In an attempt to encourage companies to research cures and treatments for diseases with small patient populations,

Congress provided a financial carrot. The first drug approved for an Orphan disease gets seven years of market exclusivity. A second drug can break that exclusivity, but only by establishing superiority over the first, a difficult standard.

At the time of the merger one would assume that each company was moving its project as quickly as it could. Post-merger, Genzyme still had the incentive to get a product to market as soon as possible, to start earning a return on its investment. So the question became the nature of the incentive to develop the second product. Genzyme could use the Novazyme compound for a comparative experiment and, allowing for potential synergies, gain the support of the relevant patient advocacy group.⁷⁴

Thompson said that the fact that the Novazyme project had been delayed was evidence that Genzyme intended to delay it.⁷⁵ This kind of odd logic crops up in various contexts.⁷⁶ “Something was delayed, therefore you intended to delay it”

is a close cousin to “Only two people are doing research in this field therefore only two people are capable of doing research in this field.” The extrapolation from observation to conclusion is unsupported. We would hardly say that because a company’s leading project failed, that the company meant for it to do so. Muris disputed Thompson’s reading of the facts.⁷⁷ From a real world perspective, we see several reasons why it would seem irrational for Genzyme to delay development of a second product.

First, anyone who has been involved in pharmaceutical R&D can verify that coming up with firm timelines for clinical trials and FDA action is very difficult. To come up with a timeline for a compound *that is not even in the clinic*, is to engage in wild guesswork. Genzyme would want to have that second product on the market at the latest by the time any ODA exclusivity on the first product expired. There also was evidence that Genzyme wanted to use the technology in the Novazyme program to develop second generation therapy for Pompe disease, and first generation products for other similar disorders.⁷⁸ All of this suggests that there was plenty of motivation to develop the second product as quickly as possible.

Another fact was that the Novazyme’s president was to run the R&D project, and his own son suffered from Pompe disease. His motivation went well beyond economics. Finally, given the length of time of the investigation, there was in effect a two-year look back at actual R&D effort, and no evidence of reduced effort (or spending).⁷⁹ The question for Muris was, one might suppose, the question for the President of Novazyme—which path promised to get an effective treatment for Pompe disease approved and on the market faster—keeping his own project independent, or joining forces with Genzyme.

What Thompson did expressly in his dissent, and others who support the use of broad innovation market analysis have done implicitly, was to assume that an analysis that may have support in one area (i.e. product markets) can be used as if it has support in another area (innovation). They treat innovation as if it was a product market, taking presumptions of anticompetitive effects from the product market realm and applying them to innovation without seeming to acknowledge the difference. Thus, they assume that having two separate research programs is *per se* better than having one, based on the idea that having two widgets on the market is better than having only one.⁸⁰ But as this analysis has tried to show in Part IV, when one tries to test that theory in the real world, it becomes very difficult to explain why more spending or more programs (no matter how weak or ill conceived) are “better” in terms of the anticipated output.

7. 2009 COMMISSIONER ROSCH SPEECH

While it is not a case, the speech by Commissioner Rosch on February 2, 2009 to the ABA Intellectual Property Conference⁸¹ is remarkable both for its candor and for its analysis.

Rosch recognizes that no court has ever invalidated a transaction purely in a purely innovation market (where there was no product at the time).⁸² The FTC raises the issue in cases, but then negotiates settlements. So the question whether an innovation market is cognizable under Section 7 has never been tested. What we have are out-licenses or divestitures of compounds which the parties view as simply a tax on the merger.⁸³

Perhaps the key observation that Rosch makes is that:

“Arguing over whether the parties to a merger have market power in an innovation market is a bit like trying to fit a square peg into a round hole. Traditional market definition analysis is, as a general matter, static by nature....innovation markets are more dynamic...an innovation market cannot be pinned down and it certainly cannot be identified with the certainty the *Philadelphia National Bank* requires.”⁸⁴

Rosch would solve the problem by sliding around it. He would find market power without defining the market first.⁸⁵ On the issue of the two-year window for entry set forth in the Horizontal Merger Guidelines then in effect,⁸⁶ the Guidelines published in 2010 eliminated the problem by eliminating two-year limit entirely⁸⁷ (still leaving the issue of how far out is too far out, of course).

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But this creates an interesting counterfactual. Has anyone ever seen a case where the merging parties have argued successfully that despite the fact that they are both in the market with products or have late stage (Phase III) compounds in research, that they should be allowed to merge because there are other companies that have compounds earlier in the pipeline (say Phase I or Phase II)? I have not seen such a case. Those earlier stage compounds are deemed to be too far away, and with too small a chance of success, to be treated as “in the market” for defense purposes. Logically, the same standard should be applied to the intervening agencies.

If people believe that this approach will let mergers with palpable anticompetitive risk get through, then we need to find a way to analyze these mergers in a manner that is consistent, predictable, and reflects the reality of competition and not just its theory.

8. 2010—Pfizer/Wyeth⁸⁸

For the purposes of this article, the interest here is not in the decision itself (no divestiture was required on any human health product or compound), but rather the Statement of the Commission which, in a little over four pages, gave a roadmap of the way the then Commission viewed research based pharmaceutical company deals.⁸⁹ The Commission analyzed the transaction in terms of actual goods, future goods, IP and Innovation.

- **Actual Goods:** In this approach, the Commission recognized that there were a small number of conditions for which Pfizer and Wyeth marketed treatments, but their products were not close substitutes for each other (indeed, the Commission said that the products were not even competitive with each other). Further, an undefined but sufficient number of other companies were competing in same markets, with products that were closer substitutes to the Pfizer/Wyeth products than were the Pfizer or Wyeth products to each other.
- **Future Goods/Future Competition:** This is the section that might have been labeled “innovation market analysis” in an earlier case. The fact that it was treated as a future goods issue is encouraging. The Commission noted that there were a small number of diseases where one company had a product and the other was developing a compound that could compete with that product in the future. The conclusion was that the Pfizer and Wyeth products were unlikely to be sufficiently close competitors to cause problems, and they would compete more closely with products of third parties.⁹⁰
- **Intellectual Property:** Would combining the IP of the two firms create a bar to others working in the fields affected? IP is property and, just like a scarce raw material, access to unblocked research avenues is critical to developing new products. The conclusion was that the bar caused by combining the two companies’ patent portfolios would not cause any greater barrier to entry than the IP held by the parties individually. The merger did not increase the bar.
- **Innovation:** The explanation here is among the fullest that the Commission gave. It first laid out some basic facts about the companies doing research in the pharmaceutical industry:

“Finally, staff evaluated whether the transaction would decrease basic research or the pace of innovation in pharmaceutical markets by eliminating a leader in pharmaceutical research and development; changing the incentives of companies performing pharmaceutical research and development; or reducing the number of potential research, marketing, or funding partners. *Pharmaceutical research and development is a dynamic field with multi-*

ple participants including both large and small traditional pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, and contract research organizations. The evidence does not indicate that the combination raises antitrust concerns in these respects.”⁹¹

What the FTC said is that there can be no shortcut here; no defining the entire pharmaceutical industry as meeting the standards in the 1995 Intellectual Property Guidelines for defining an innovation market.⁹²

R&D is dynamic, broad based, and worldwide. In every R&D divestiture of which the writer is aware, the program is divested worldwide. And certainly the pool of knowledge and talent is a worldwide one, not simply in terms of hiring employees but in terms of networking people from various companies and universities.⁹³ Individual companies set up networks of collaborations⁹⁴ and broader coalitions have formed.⁹⁵ There are examples of the pooling of data across companies⁹⁶ and sharing information and research with non-profit partnerships targeting one or more diseases.⁹⁷ And this is all in addition to the more traditional partnerships between one company and academic scientists and institutions.⁹⁸

VIII. A View from Brussels

Because the structure of European competition law applicable to agreements and cooperation short of mergers is set up with broad prohibitions but with the possibility for exemptions,⁹⁹ the members of DG Competition also have had to deal with some of the issues highlighted in this article in the process of formulating Block Exemptions (“BEs”) and Guidance documents.¹⁰⁰ The BEs have market-share thresholds, such that if the companies exceed those thresholds the BE does not apply (although that does not mean that the agreement violates the law).

The 1984 and 2000 R&D BEs proposed to have different thresholds apply for the exemption depending on whether the parties collaborating were competing in the relevant market.¹⁰¹ But this raised the primary issue: if the work was in R&D, there was no “market” where you could intelligently measure “market shares.” The Commission went back to what it could measure—the shares of the markets for the existing products that were deemed capable of being improved or replaced by the joint R&D products (if they succeeded).¹⁰² If the R&D was directed at a market where the parties had existing goods capable of being improved or replaced by the R&D project outcome, then the BE would only apply if the combined share of that product market did not exceed 25 percent. If the R&D was directed at a field in which neither party had any products to be replaced or improved, the BE applied regardless of the structure or amount of other competition in that R&D sector.¹⁰³

There is a clear recognition that a market-share type of test cannot be applied directly to R&D (or innovation). In fact, the categories of market share analysis really don't apply to R&D itself, which is why the Commission recognized that if the R&D was aimed at an area where neither company had a product, it could come within the BE regardless of how many other companies were, or were not, working in that field.

When it comes to the more general approach of the Guidelines on Horizontal Cooperation Agreements, both the 2001 and the 2010 versions, there is broader language but still a recognition that any rules have to be tied to something tangible. At Paragraph 114 of the 2010 Guidelines there is the following formulation:

“In the first scenario, which is, for instance, present in the pharmaceutical industry, the process of innovation is structured in such a way that it is possible at an early stage to identify competing R&D poles. Competing R&D poles are R&D efforts directed towards a certain new product or technology, and the substitutes for that R&D, i.e. R&D aimed at developing substitutable products or technology for those developed by the co-operation and having similar timing. In this case, it can be analysed if after the agreement there will be a sufficient number of remaining R&D poles. The starting point of the analysis is the R&D of the parties. Then credible competing R&D poles have to be identified. In order to assess the credibility of competing poles, the following aspects have to be taken into account: the nature, scope and size of possible other R&D efforts, their access to financial and human resources, know how/patents, or other specialised assets as well as their timing and their capability to exploit possible results. An R&D pole is not a credible competitor if it cannot be regarded as a close substitute for the parties' R&D effort from the viewpoint of, for instance, access to resources or timing.”¹⁰⁴

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IN THAT FIELD.

The Guidelines also provide examples that are interesting, in large part, because they appear to reflect real world scenarios. For example, Section 142, example 2, deals with a situation where the parties are collaborating on research on a new treatment for a disease, one party has a large share of the existing product market for treatments for that disease, patents are expiring in five years, there are only two other research poles, and yet the deal should and would be cleared.¹⁰⁵ There is recognition in this example and the analysis following it of

the realities of the prescription drug industry that is almost unique in the official literature.

Unfortunately, one looks in vain for any *a priori* way of determining how many R&D poles are enough. While this is no doubt frustrating from a theoretical standpoint, it may indeed reflect the approach to be preferred here. As the example makes clear, the number of R&D poles required to allow clearance of collaboration depends on the facts of the situation—the market, the patent protection, the needs to get the research to fruition. All of these are individualized concerns. What is a “sufficient” number of competing R&D poles will depend on the facts of the case.¹⁰⁶

In 1994 Pfizer signed a joint venture agreement to co-promote Eisai’s product, Aricept (treatment for Alzheimer’s Disease). Both companies had R&D projects in the field, as did seven other companies, at least two of which were on the same time line as the Pfizer and Eisai projects (Eisai being a year or two ahead of Pfizer). The Pfizer compound was assigned to Eisai and kept as a backup, if needed. By the time that the notification was filed to the commission (1998), the Eisai product had already been launched by the parties. The product was the first effective treatment for Alzheimer’s disease, and to the extent that this was a market, Aricept certainly had a dominant share. Out of the seven other companies, only one of the projects led to a successful product shortly after Aricept. The Commission cleared the transaction under then Article 81(3) with a comfort letter.¹⁰⁷

What makes this case unusual is that at the time of the notification, the product was already on the market and succeeding. The Commission, correctly, went back and looked at the agreement at the time that it was made (an *ex ante* approach) and held that while the co-promotion agreement did reduce the number of R&D poles, at the time that the deal was done there were sufficient other poles and, in looking at the potential for exemption, the Commission saw the obvious consumer benefit that the co-promotion arrangement had made in getting the product to market. They judged that the parties should not be penalized for their success in being the first ones to market with an important new therapy.¹⁰⁸

Finally, the 2004 Horizontal Merger Guidelines do not speak of innovation markets as such. They do speak of what appears to be a future goods market, but in terms of changes to a “specific product market” that can be “reasonably predicted.”¹⁰⁹ They go on to state:

“In markets where innovation is an important competitive force, a merger may increase the firms’ ability and incentive to bring new innovations to the market and, thereby, the competitive pressure on rivals to innovate in that

market. Alternatively, effective competition may be significantly impeded by a merger between two important innovators, for instance between two companies with “pipeline” products related to a specific product market. Similarly, a firm with a relatively small market share may nevertheless be an important competitive force if it has promising pipeline products.”¹¹⁰

The key for the analysis here is that the DG Competition approach does tie back to the real, tangible world, which is where effects will have to be measured.

IX. A Proposed Theory of Innovation Markets

Any theory of innovation markets should meet two tests. First, it needs to fit within a broader theory of markets, since it must be consistent with them to avoid an ad hoc, unprincipled approach to its application. Second, the theory needs to deal with the reality of the markets to which it supposed to apply, not just the theoretical constructs about them.

Having reviewed the swings and variations in the application of innovation market theory, and the times when that theory is based on assumptions that simply do not hold in the real world, our analysis drives to a somewhat surprising and modest conclusion. The drafters of the 1995 Intellectual Property Guidelines had it pretty much right. And the FTC in its discussion of the Pfizer/Wyeth merger of 2009 seemed to agree.¹¹¹

But while the traditional FTC application of innovation market theory may be incoherent and frustrating, it does let the agency try to catch matters that do not fit well, or at all, within more traditional categories. It is an ultimate gap filler. This type of thinking flows through many of the FTC Consent Orders discussed earlier where standard antitrust verbiage is used in situations where it really doesn’t apply.¹¹²

A gap filler is not necessarily invalid or illegitimate. But if it truly is to be gap filler, rather than something that will expand without limits to fill any desired enforcement role, there have to be some boundaries on where the theory can go. At the end of the exercise, it should be possible to create a working taxonomy or classification system that will enable us to see when innovation market analysis is appropriate, and how to do that analysis.

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A. ACTUAL GOODS

This is a standard antitrust analysis. When there are existing goods, the agencies can base a case on them using established and tested principles. There is no need to go searching for other theories to use.¹¹³

B. FUTURE GOODS

Where there is a product on the market and a future product in research, is entry of the latter sufficiently certain and timely to make it part of the product market for analytical purposes? In terms of timeliness, the 1992 Horizontal Merger Guidelines set a two-year limit on entry to be considered part of the market, and the 2010 replacements, while eliminating the two years, keep the concept of timely entry as defining a market participant.

In terms of certainty, at least as far as the pharmaceutical industry is concerned (and recall that is where almost all of the innovation market cases take place), compounds at Phase III and above would seem to be a rational cut-off point (greater than 50 percent chance of success; time to approval 2-4 years).¹¹⁴ There might be some flex in the definition, depending on the facts of a given situation. If the FDA is reviewing and approving drugs faster for a given disease or unmet need, then there may be a good reason for including Phase II compounds as future goods.¹¹⁵

Future goods is an underutilized category, often improperly slighted in favor of innovation market analysis. All of the groundwork for such an analysis was present in *Roche/Genentech* and *AHP/Cyanamid*. Had the agency applied a future goods analysis, it would have concluded that no intervention was required and, indeed, the potential products were so far away from the market that the risk of both of them even coming to market was so remote that requiring a remedy was unjustified and simply added to the risk that no product would survive.

And remember our earlier counterfactual. Logically, either a compound is close enough to the market to “count” or it is not, regardless of whether the view is from the FTC or the merging parties. I have seen no case where the merging parties have argued successfully that, despite the fact that they are both in the market with products or have late stage (Phase III) compounds in research, they should be allowed to merge because there are other companies that have compounds earlier in the pipeline (say Phase I or Phase II)? Those earlier stage compounds are deemed to be too far away, and with too small a chance of success, to be treated as “in the market” for defense purposes. For the same reason, those earlier stage compounds should not “count” to justify agency intervention.

C. INTELLECTUAL PROPERTY

An argument that a merger creates a patent blockade greater than the patent estates of the individual participants is not always a simple one to prove. But

assuming that the factual hurdle can be jumped, there is no theoretical reason to treat IP as different from any other kind of property.¹¹⁶ But if the agencies are talking about IP, there is no need to talk about innovation markets. Patents are things that one can count, read, buy, sell, and license. It may not be easy to monopolize an IP market. But one does not make the analysis any easier or any better by dragging in innovation.

That leaves the last category, the last block in the square. We are left with innovation, and how to deal with it.

D. INNOVATION/RESEARCH & DEVELOPMENT

It is highly unlikely that pure innovation represents a market that would be defensible on traditional competition law terms, much less one in which one could calculate market shares and Herfindahl indices. Perhaps this is one reason why no pure innovation market case has ever reached a court decision.¹¹⁷ Indeed, there are major problems even trying to define what is meant by innovation, how it could or should be measured, and how much innovation is better or worse than any other amount. Even then, there is the question of how much innovation is out there, or available, and that includes the internet's existence, the linked-in scientific community, and the ability of any company with money to access the relevant science.

BUT IF THE AGENCIES ARE TALKING ABOUT IP, THERE IS NO NEED TO TALK ABOUT INNOVATION MARKETS.

This may well be why the IP Guidelines, and the European Commission Block Exemptions, came at the issue from the flank. They limited innovation market inquiries to cases where the parties have unique access to necessary tangible assets; where the capability to engage in the relevant R&D can be associated with specialized assets or characteristics of specific firms. This is the key. Once the analysis gets back to looking at tangible assets, one can ask what is required to do the research, who has access to such assets, and whether others can get such access. The analysis is back on solid ground.

X. The Revised Innovation Market Theory Applied

This analysis leads to a theory that is both internally consistent and consistent with the external reality of the marketplace: an innovation market analysis is only applicable when the facts do not permit analysis in terms of actual goods, future goods, or IP, and then only applies where there is limited access to necessary tangible assets in order to work in the field.

Would the application of the proposed new theory have made a difference in the case outcomes and, if so, how and why? Hindsight provides an enormous

advantage in making this analysis. It allows a look at what actually occurred in the marketplace—to see whether the remedy applied did, in fact, lead to increased competition, more products on the markets, and all of the attendant benefits that innovation market intervention is supposed to provide.

Based upon that review, of the eight key cases that were reviewed above, the results would not have changed in five of them (*Smog Control Devices*; *U.S. v. G.M.* (truck transmission); *Glaxo/Wellcome*; *Ciba/Sandoz*; and *Genzyme/Novazyme*), although the rationale for intervention or non-intervention would have been different in some.

In the three cases where the result would have changed (*Roche/Genentech*; *American Home/American Cyanamid*; and *Pfizer/Warner Lambert*) the approach presented here counseled against the intervention that took place. Had the FTC looked at the cases as future goods matters, they would have recognized that no intervention was justified. And in each case the factual look back supports such a non-interventional approach.

At the end of the day, the question is whether competition law agencies should intervene in R&D at a very early stage based on what is almost a theological belief that society is better off with two small projects than one larger one. The underpinnings of that belief are shaky, even if there was an agreed upon measuring rod for R&D, apart from looking at what products actually make it to market.

WHAT HAS TO BE REALIZED AND ACKNOWLEDGED IS THAT THERE IS A VIRTUALLY INFINITE SET OF MEDICAL PROBLEMS TO BE RESEARCHED. THE AREAS THAT HAVE LARGER POTENTIAL PATIENT POPULATIONS AND POTENTIAL FINANCIAL RETURN WILL ATTRACT GREATER R&D EFFORTS.

For example, where the scientific problems are extremely difficult, even large companies have found it more productive to pool their resources rather than exploring every dead end alone. Perhaps the most famous example of this is the 1993 Inter-Company Collaboration for AIDS Drug Development.¹¹⁸ And in 2010, companies agreed to share data on clinical trials in Alzheimer’s drug testing.¹¹⁹

This is not to suggest that it would be good policy to force the creation of one large pharmaceutical company. But it is to say that we should be wary of intervening in the decision of these companies to allocate their capital and their efforts in one area rather than another. It should not shock us that very few firms choose to invest in research to find a cure for Pompe Disease. What has to be realized and acknowledged is that there is a virtually infinite set of medical problems to be researched. The areas that have larger potential patient populations and potential financial return will attract greater R&D efforts.

The narrower one defines the market, the fewer players one will have. Thus, a field defined as “R&D into blocking cancerous tumor growth,” will have many

participants. A field defined as “Impeding drug cell signaling pathways impacted in rapid cell division” (a subset of the first field), will have fewer participants. This is simply a function of how analysis works—no more and no less. It is one approach out of many. There is nothing malignant or even mysterious about this. The narrower the focus, the fewer the objects there will be in the field. If the question posed was how many companies were working on a cure for Pompe Disease using compound NZ-1001, there was only one member of that set; Novazyme. But that fact tells us very little by itself.

XI. A Proposal

Innovation market theory, as it has been applied to date, rests on a flawed foundation. It is a conceptual stretch to cover the situation where more established theories do not seem to apply. And, at least as far as the research-based pharmaceutical industry is concerned, the theory relies on assumptions about how these companies behave that are contradicted by the facts that drive behavior in the marketplace.

In its analysis of cases to date, the FTC seemed to be unduly concerned that transactions might eliminate competition between two or more early stage development projects even when history demonstrated it was highly unlikely that either (much less both) project(s) resulted in a product on the market. Recognizing that a traditional future goods analysis did not support intervention (and therefore did not solve the perceived problem), the agency stretched the future goods rules by cloaking them in innovation market language. But, rather than increasing innovation, that approach may well have hindered it. Once it is recognized that there is no necessary harm in these cases, the need to stretch to find a remedy goes away.

The approach suggested here is one of humility and practicality. There is a role for innovation market analysis, but it is a modest one. Rather than constitute a free-roving charter to substitute the judgment of antitrust regulators for decisions of the private parties involved, it should be used to allow intervention where such action can be justified in terms of practical tangible impact.

Economists and lawyers have experience with traditional actual goods markets. There is a large body of data on prices, demand, and firm behavior. There are data on future goods and the impact of goods on the edge of the market as well as on the behavior of participants with goods on the market (and real time frames associated with that data—which is what led to the two-year clause in the

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1992 Merger Guidelines). And once it is accepted that IP is a form of asset with certain definable characteristics, antitrust lawyers and economists can talk about how to avoid multiplication of the statutory grants through merger. But as Commissioner Rosch noted,¹²⁰ innovation is a very different kind of animal.

Unless an analysis ties innovation to output, there is no verifiable way to know what to measure, how to measure it, how to encourage it, or what the optimum conditions are for it to grow and flourish. If one university hires five experts on the causes of Alzheimer's disease, does that speed up, retard, or leave unchanged the time line for coming up with an effective cure? What is the basis for your answer? If an observer hopes that the mass hiring speeds up the finding the cure process, would he or she say the same thing if one company hired those same five scientists? What if one company partnered with five universities? What if five companies pooled their resources?

Asking these questions throws a light on an underlying core issue. The question isn't so much whether one deal is good or bad, or even whether it helps innovation or retards it. The question is how one would ever be able to predict the outcome with any degree of confidence. The FTC has jumped that question by making presumptions about how the parties would or should behave. But those presumptions have been shown to be unsupported, leaving the issue of showing a potential benefit from intervention open.¹²¹

So the conclusion of this analysis and the look back at applicable cases is a plea for a bit of humility on the part of the competition law enforcement groups. Where there are actual goods markets, future goods markets (properly defined) or IP markets, then the agencies can apply their traditional theories and have some confidence in the outcome. But when one looks at innovation and the innovative process, it is crucial to recognize that there is much that simply is not known. On the taxonomy and innovation market definition suggested here, the analysis ties to limited physical assets. Those can be found, counted, and costed out. But to go further, and to continue to try to control the actual innovative process itself by applying theories and presumptions, risks doing far more harm than good. ▼

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- 1 Speech by Commissioner Rosch on February 2, 2009 to the ABA Intellectual Property Conference; <http://www.ftc.gov/speeches/rosch/090205innovationspeech.pdf> (hereinafter "Rosch Speech") at 13-14. This may be why the theory has never been asserted successfully in a litigated case.
 - 2 It is not always simple to answer these questions. But that is not an excuse for a failure to try. Indeed, the attempt itself gives us some valuable information about the theories in play.
 - 3 1995 Antitrust Guidelines for the Licensing of Intellectual Property ("IP Guidelines") §3.2.3, *available at* <http://www.justice.gov/atr/public/guidelines/0558.htm>
 - 4 The literature on innovation market analysis is rich and full. While we will spend most of our time examining the cases themselves, we will make multiple citations to certain works: Abrantes-Metz et

al, *Empirical Facts and Innovation Markets: Analysis of the Pharmaceutical Industry*, ANTITRUST SOURCE 1 (March 2005) (hereinafter "Abrantes-Metz"); Carrier, *Two Puzzles Resolved: Of the Schumpeter-Arrow Stalemate and Pharmaceutical Innovation Markets*, 93 IOWA L.R. 393 (2008) (hereinafter "Carrier"); Gotts & Rapp, *Antitrust Treatment of Future Goods*, ANTITRUST 100 (Fall 2004) (hereinafter "Gotts and Rapp"); and Rapp, *The Misapplication of the Innovation Market Approach to Merger Analysis*, 64 ABA ANTITRUST L.J. 19 (1995) (hereinafter, "Rapp"). For those interested in perhaps the fairest and certainly the deepest analysis done in the field, see MARCUS GLADER, *INNOVATION MARKETS AND COMPETITION ANALYSIS: EU COMPETITION LAW AND US ANTITRUST LAW* (2006) (hereinafter "Glader").

- 5 U.S. v. Automobile Manufacturers Association, 307 F. Supp. 617 (C.D. Cal 1969), appeal dismissed sub nom City of New York v. U.S., 397 U.S. 248 (1970).
- 6 U.S. v. General Motors Corp., Civ. No.93-530 (D. Del. filed 11/16/93) (hereinafter "GM Complaint").
- 7 See speech of Anne. K. Bingaman, Antitrust and Innovation in a High Technology Society (January 10, 1994); www.usdoj.gov/atr/public/speeches/0108.htm.
- 8 Back in the 1960s and 1970s the Department of Justice made a similar attempt to create law out of speeches about patent licensing terms. The approach was to convince companies not to use certain terms in patent licensing by simply stating that such terms were illegal, without actually having to bring and win any cases. It was referred to as "Luncheon Law," as the speeches often followed a lunch. Neither then, nor now, did it provide anything in the way of rigorous analysis. See Bernard, *The 2008 EC Sector Inquiry Regarding Pharmaceuticals: What Does It Mean From a Research-Based Company Perspective*, GLOBAL COMPETITION POL'Y 10-11 (November 2008) at pages 10-11. Richard Rapp believed that in most cases invoking "innovation markets" was just a way of talking about future products/potential competition but going farther back into the R&D pipeline; Rapp, *supra* note 4 at 2. Indeed, the cases are consistent with such a definition. But Rapp did not mean that such an approach was valid or correct. Those are issues that will be explored in the course of this article.
- 9 IP Guidelines, *supra* note 3, §3.2. It is interesting that the Guidelines, at §3.1, phrase their concern in terms of:

An arrangement that effectively merges the research and development activities of two of only a few entities that could plausibly engage in research and development in the relevant field.... (emphasis supplied).

The focus is on companies that *could* do work in the field, not simply those that happen to be working there at a given point in time. This point is critical, and has all too often been overlooked or ignored in the cases.
- 10 One way to look at this is to consider innovation as a driver of economic growth, as many have. See Bernard & Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements*, 15 FEDERAL CIRCUIT BAR J. 617, 618 (2006); Carrier, *supra* note 4 at 399 and note 8. But this is still an abstraction. What is being acquired or divested is something specific, and should lead to something concrete at the end of the day.
- 11 Rosch speech, *supra* note 1 at 9.
- 12 Perhaps the most notable example of this point is far outside of the competition law universe, i.e. the Manhattan Project to develop the atomic bomb in World War II. Multiple projects were yoked together and coordinated by the government with the end of developing a workable bomb as soon as possible. See <http://www.cfo.doe.gov/me70/manhattan/> ; <http://nuclearweaponarchive.org/Usa/Med/Med.html>. A single project was deemed to be the most efficient and the best way to get to the goal of having a workable "product" for the market. But note that once the debate shifts to how to best get a research project to market, we are talking the language of future goods markets, not innovation *per se*.

- 13 This is a point that comes back strongly in Commissioner Muris' opinion in the Genzyme case *available* at <http://www.ftc.gov/os/2004/01/murisgenzymestmt.pdf> (hereinafter "Muris Opinion") at 2-3, 5-6. From an intervention standpoint, the approach may best be asymmetric—if there are many people working in a field, then the presumption should be to let parties determine their own allocation of research capital and time. But the converse does not mean that action should be taken. The fact that there are relatively few people actually working in a field is not a sufficient cause for intervention.
- 14 Some analyses seem to want to do it in reverse—enough R&D is that amount that provides for the (eventual) launch of more than one product in a field. The problem with this is that it is not applicable *ex ante*. At the time that decisions are being made about requiring divestitures the theory does not provide us with any way to predict whether such divestitures will be helpful or harmful.
- 15 *But see* Rapp, *supra* note 4 at 34 and the commentary on the amount of money that GM spent over time and the lack of reward. This may be another asymmetrical situation—if you spend little money, you may not get results. But simply spending a lot of money doesn't guarantee any better outcome.
- 16 How do you distinguish a major invention from a minor one? How do you balance them?
- 17 If you adopt this approach, you then need to figure out how to compare cell phones, cameras, deep seas drilling tools, and prescription drugs.
- 18 Also, Goodhart's Law cautions us that once a social or economic indicator or other surrogate measure is made a target for the purpose of conducting social or economic policy, it then will lose the information content that would qualify it to play such a role. See http://lesswrong.com/lw/1ws/the_importance_of_goodharts_law/. While originally applied to monetary policy, it has broader meaning.

That is, once you start measuring GDP as a way of gauging social welfare, people will start to figure out ways to make GDP go up without improving social welfare (say, by swapping dirty financial derivatives). Once Google starts measuring inbound links as a way of evaluating the importance of web-pages, people will figure out how to increase the inbound links to unimportant pages (splogging, blogspam). And once you measure fat or calorie content as a proxy for the healthfulness of food, manufacturers will figure out how to decrease fat and calories without making the food more healthful (reducing fat by adding sugar, reducing calories by adding poisonous artificial sweeteners). <http://boingboing.net/2010/04/29/goodharts-law-once-y.html>.

In the current case, if the number of compounds in development is "the" measure of innovation, then Goodhart's Law teaches that we can expect that more compounds will be generated. What it will not say is whether that greater number of compounds truly correlates with greater innovation, other than in the tautological sense that "higher number equals more innovation" by definition.
- 19 This is something that our European colleagues seem to have accepted. See 2010 Draft Horizontal Cooperation Guidelines, *infra* note 104, at §§10, 41, and 106. The 2010 revised version of the DOJ/FTC Horizontal Merger Guidelines, *infra* note 87, tries to suggest ways to minimize the importance of the market. While a full discussion of this debate is beyond the scope of this article, it is important to note that the statute speaks of a "line of commerce." Softening guidelines doesn't change the underlying law.
- 20 Since there are no existing products in the innovation market analyses that have been put forth, economic hypotheses based on pricing impacts and diversion ratios logically have no application here.
- 21 See Rapp, *supra* note 4 at 36.
- 22 IP Guidelines, *supra* note 3, §3.2.3.
- 23 Rapp, *supra* note 4 at 37.

- 24 In the author's experience, when Pfizer acquired Pharmacia in 2003, Pfizer fought very hard to retain an agreement that Pharmacia had with Altana to develop roflumilast, viewing the compound as a potential complement in the treatment of Chronic Obstructive Pulmonary Disease. While Pfizer succeeded at the FTC, the compound then did not succeed in the clinic. In 2005 Pfizer terminated the agreement and the compound reverted to Altana; see *Daxas deal leaves Altana short of breath, available at* http://www.pharmiweb.com/features/feature.asp?ROW_ID=624 .
- 25 While someone might suggest that it is theoretically possible to sign up all of the key researchers in a field to long-term exclusive employment contracts, given the breadth of science around the world, this risk does not seem to be a realistic possibility.
- 26 Carrier, *supra* note 4. While the conclusions reached by Carrier are not the same as those reached in the current article, I adopted his approach of deriving a theory and then testing it against what actually happened in the real world.
- 27 *Id.* at 418-420; see also Gots & Rapp, *supra* note 4 at 101. If there is anything like a consensus in the field, this is it.
- 28 See, e.g., Case COMP/M.1846, Glaxo Wellcome/SmithKline Beecham (2000) at ¶190, *available at* <http://lib.hebust.edu.cn/ywyfzsk/zsk/pharm-docum/b011.pdf> .
- 29 See sources collected in Carrier, *supra* note 4 at 411-414.
- 30 See, e.g., Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, Duke University, 2002; *available at* http://levine.sscnet.ucla.edu/archive/grabow-patents_innov.pdf.
- 31 See, e.g., DiMassi et al, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151,162 (2003).
- 32 There are journals dedicated to following these developments and deals. See, e.g., FIERCE BIOTECH, a daily on-line publication *available at* http://www.fiercebiotech.com/?utm_medium=nl&utm_source=internal. The flow of alliances and acquisitions is unending. The facts simply do not support any assumption that a few large companies are the only ones capable of or doing research in a field.
- 33 See GW Law School report at <http://www.law.gwu.edu/Academics/FocusAreas/IP/Pages/Cloning.aspx>.
- 34 Carrier, *supra* note 4 at 401 (citing the IP Guidelines Section 3.2.3).
- 35 For example, Pfizer paid \$1.3 billion to acquire a company, Esperion, that had one promising phase II compound <http://www.cnn.com/2003/BUSINESS/12/21/us.pfizer.reut/>. This is not unique to Pfizer. See generally <http://www.businesschemistry.org/article/?article=113>. And the saga of the acquisition of OSI is instructive. See text accompanying notes 62 - 64, *infra*.
- 36 Price competition among generic drug sellers in the United States is vicious. Many large chains in the United States are now offering a 30 day supply of the most popular generic drugs for well under \$10, and some at half that price or less. See the report of the National Conference of State Legislatures (January 2009), *available at* <http://www.ncsl.org/IssuesResearch/Health/GenericDrugPricingandStates2009edition/tabid/14440/Default.aspx>. See also <https://webapp.walgreens.com/MYWCARDWeb/pdf/Value-PricedGenericsList.pdf>.
- 37 See, e.g., the impact on a major patented cholesterol lowering product when a competitor went off patent; http://www.forbes.com/2007/07/18/pharmaceuticals-pfizer-lipitor-biz-sci-cx_mh_0718_pfizer.html
- 38 This issue is not unique to any one company. It is simply a fact of life in the research-based drug

industry that even late stage projects fail. Pfizer had a promising compound in phase III for boosting “good” cholesterol. It would have opened up a new market, and complimented an existing product that lowered “bad” cholesterol. On November 30, 2006 the Pfizer CEO declared that the compound would be a potential blockbuster. On December 2, 2006 the project was killed based on side effects that had just come to light. The project cost over \$800 million by the time it ended. <http://www.fiercepharma.com/special-reports/pharmas-biggest-flops/torcetrapib-pharmas-biggest-flops>. See also Eli Lilly and Bristol-Myers Squibb regarding the failure of Erbitux for treatment of colon cancer; http://www.dnaindia.com/health/report_colon-cancer-drug-failure-challenges-assumptions_1392852, and Novartis and Antisoma with respect to their Phase III compound for non-small cell lung cancer, http://www.dnaindia.com/health/report_colon-cancer-drug-failure-challenges-assumptions_1392852.

- 39 See Novartis, and the successor to its very successful product, Gleevec, http://www.fiercepharma.com/story/data-aids-novartis-push-replace-gleevec-tasigna/2010-06-04?utm_medium=nl&utm_source=internal.
- 40 Genzyme is a case study on real world facts. The issue was treatment for Pompe Disease, a fatal condition affecting a relatively small number of people, for which there was no treatment. The only companies working in the field were Genzyme, which had experience with the type of approach involved, and Novazyme. For reasons that will be discussed later, the FTC elected not to challenge the deal. On the facts, that seems to have been the right decision (although one Commissioner dissented on what we can call traditional antitrust grounds about not allowing mergers to monopoly). This case, and the theoretical battle over what is best for innovation, will be discussed further below.
- 41 Abrantes-Metz, *supra* note 4 at 5; Rapp & Gotts, *supra* note 4 at 101.
- 42 *Guidelines on the Application of Article 101 of the Treaty on the Functioning of the European Union to Horizontal Cooperation Agreements*, at ¶¶117-120; available at http://ec.europa.eu/competition/consultations/2010_horizontals/guidelines_en.pdf. See also the case law cited earlier, *supra* note 28.
- 43 IP Guidelines *supra* note 3, Section 2.1. There may be interesting factual issues where a patent covers more than one area, or has application in more than one area. But this can arise with any asset.
- 44 It is encouraging that this analysis is both consistent with, and helps to explain, the FTC clearance and analysis in the recent Pfizer/Wyeth transaction; see Statement of Federal Trade Commission Concerning Pfizer/Wyeth, No.091-0053, available at <http://www.ftc.gov/os/caselist/0910053/091014pwyethstmt.pdf>.
- 45 There is a rich library of work on the distinction between Type 1 errors (prohibiting something that should be allowed) and Type 2 errors (allowing something that should be prohibited). See *generally* INTERNATIONAL ANTITRUST LAW AND POLICY, THE 2008 FORDHAM COMPETITION LAW INSTITUTE (B. Hawk, ed.) at Chapters 16-19 (articles by John Fingleton & Ali Nikpay; David Lewis; Paul Lugard; and Daniel Rubinfeld). That debate is beyond the scope of this article. For our purposes, the key is that given the inability to define the conditions for encouraging innovation, intervention should be a last, rather than first, resort.
- 46 IP Guidelines, *supra* note 3, Section 3.2.3; Carrier, *supra* note 4 at 401.
- 47 For an example of what is out there, see WORKING TOGETHER, CREATING KNOWLEDGE (The University-Industry Research Collaboration Initiative)(2001) available at <http://www.acenet.edu/bookstore/pdf/working-together.pdf>.
- 48 The reference is to a legendary children’s book (and movie), *The Wizard of Oz*, about a little girl named Dorothy who is whisked away from her home in Kansas by a tornado and deposited in the magical Land of Oz. After numerous adventures, she makes it home to Kansas safe and sound. See *generally* <http://www.imdb.com/title/tt0032138/synopsis>

- 49 In re: Roche Holding Ltd., 113 FTC 1086 (1990).
- 50 Carrier, *supra* note 4 at 430-431.
- 51 See Abrantes-Metz, *supra* note 4 at 5; Carrier, *supra* note 4 at 416-419.
- 52 Carrier, *supra* note 4 at 431.
- 53 In re: American Home Products, 119 FTC 217 (1995).
- 54 Carrier, *supra* note 4 at 432.
- 55 *Id.* at 432-433.
- 56 In re: Glaxo, 119 FTC 815 (1995).
- 57 See <http://www.centerwatch.com/drug-information/fda-approvals/drug-details.aspx?DrugID=348>.
- 58 By 1999 Glaxo still had 83 percent of the sales of migraine treatment products, with Imitrex. Zomig (the former Wellcome compound) did reach the market, and had a 7 percent share at this time. By 2006 Imitrex still had a 56 percent share, but three other companies had share of at least 10 percent each. See Carrier, *supra* note 4 at 434.
- 59 In re: Ciba-Geigy Ltd., 123 FTC 842 (1997).
- 60 In re: Pfizer Inc., Case No. 001-0059 (2000), *available at* <http://www.ftc.gov/os/caselist/c3957.shtm>. Note that when the same acquisition was considered by the European Commission, the authorities there did not agree with the FTC's view either on market definition or on the impact of phase I compounds. The EC found no remedy required in the oncology field. See Case No COMP/M.1878, Pfizer/Warner Lambert at ¶¶42, 77-80 (2000) *available at* http://ec.europa.eu/competition/mergers/cases/decisions/m1878_en.pdf.
- 61 <http://www.centerwatch.com/drug-information/fda-approvals/drug-details.aspx?DrugID=867>.
- 62 <http://www.thepharmaletter.com/file/47058/roche-and-genentech-sign-oncology-deal-with-osi-valued-at-187-million.html>.
- 63 <http://www.businessweek.com/ap/financialnews/D9G7QS901.htm>.
- 64 <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108383.htm>.
- 65 FTC Complaint, ¶29.d. at <http://www.ftc.gov/os/2000/06/pfizercmp.htm>.
- 66 See, e.g., http://www.fiercepharma.com/story/gsk-cancer-pill-tyverb-falls-short-nice/2010-06-09?utm_medium=nl&utm_source=internal.
- 67 See, e.g., the decision of the U.K agency denying reimbursement on cost effectiveness grounds of several new compounds; http://www.fiercepharma.com/story/avastin-gets-new-thumbs-down-nice/2010-07-09?utm_medium=nl&utm_source=internal; <http://www.medscape.com/viewarticle/712971>. See also the debate of U.S. healthcare officials deciding on whether to pay for a prostate cancer vaccine; http://www.fiercevaccines.com/story/dendreon-shares-routed-news-medicare-provenge-review/2010-07-01?utm_medium=nl&utm_source=internal.

- 68 Interestingly, the European Commission took a position very much like the one recommended here in the Pfizer/Warner Lambert case, holding that the competition in later phase compounds made any adverse impact from the acquisition too speculative to base action upon. See Case No COMP/M.1878, Pfizer/Warner Lambert at ¶¶42, 77-80 (2000) available at http://ec.europa.eu/competition/mergers/cases/decisions/m1878_en.pdf.
- 69 FTC Closes its Investigation of Genzyme Corporation's 2001 Acquisition of Novazyme Pharmaceuticals, Inc. (2004); <http://www.ftc.gov/opa/2004/01/genzyme.shtm>.
- 70 *Id.*
- 71 In April 2006 the FDA approved the first such treatment, Genzyme's Myozyme; <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108645.htm>.
- 72 Muris Opinion, *supra* note 13 at 6.
- 73 *Id.* at note 29.
- 74 *Id.* notes 42 and 43.
- 75 Thompson Statement In Genzyme, at 5, available at http://www.ftc.gov/os/2004/01/thompson_genzymestmt.pdf.
- 76 Logicians refer to it as the fallacy of "post hoc, ergo propter hoc" which loosely translates as "After this, therefore because of this." See <http://www.skepdic.com/posthoc.html>.
- 77 Muris Opinion, *supra* note 13 at 23.
- 78 Genzyme Press Release of August 7, 2001, quoted at Muris Statement, *supra* note 13, at note 34.
- 79 Muris Opinion, *supra* note 13 at 17.
- 80 This is not unique to Thompson. It flows through many of the supporters of broad use of innovation markets. See, e.g., Dennis A. Yao & Susan S. DeSanti, *Innovation Issues Under the 1992 Merger Guidelines*, 61 ANTITRUST L.J. 505, 510 (1993) (speaking of preserving innovation is the benefits that arise from having multiple paths towards the same goal). And see *In re: American Home Products*, 119 FTC 217 (1995) at ¶13 (speaking of the HHI for a market for the development of something that does not yet exist); available at http://www.ftc.gov/os/decisions/docs/vol119/FTC_VOLUME_DECISION_119_%28JANUARY_-_JUNE_1995%29PAGES_217-315.pdf.
- 81 Rosch speech, *supra* note 1.
- 82 *Id.* at 13-14 and note 37.
- 83 One primary reason that companies agree to such a tax is, again, a factor of real world business. They want to close their deal. The longer things stand open, the more disruption there is, the more good people they lose, and the longer it takes to get the businesses integrated. See, e.g. <http://seeking-alpha.com/article/162831-delay-in-oracle-sun-merger-hurts-both-parties>; <http://www.v3.co.uk/v3/news/2251658/sun-cuts-jobs-blaming-merger>. Further, a major transaction may not hold in place for the six months or more that it may take to get an FTC decision, and closing simply on the basis of no Federal Court injunction stopping you is a risky process. Finally, once the parties agree to the terms of a settlement, they have little interest in delaying things further by arguing over the terms of and theories underlying the proposed complaint. See, Kovacic & Winerman, *Competition Policy and the Application of Section 5 of the Federal Trade Commission Act*, 76 ANTITRUST L.J. 929, 941 note 36 (2010).

- 84 Rosch speech, *supra* note 1 at 21.
- 85 *Id.* at 22.
- 86 1992/1997 Horizontal Merger Guidelines Section 3.2, available at <http://www.justice.gov/atr/public/guidelines/hmg.htm>.
- 87 See 2010 Horizontal Merger Guidelines, available at <http://www.ftc.gov/os/2010/08/100819hmg.pdf>.
- 88 <http://www.ftc.gov/os/caselist/0910053/index.shtm>.
- 89 <http://www.ftc.gov/os/caselist/0910053/091014pwyethstmt.pdf>.
- 90 Admittedly, the conclusions were based on non-public data so it is difficult to evaluate how far the Commission has moved towards a predictable theory of future goods and when a compound should “count” for this purpose. But the frame of the analysis is right.
- 91 FTC Statement in Pfizer/Wyeth, *supra* note 89 at 4, emphasis supplied.
- 92 Intellectual Property Guidelines, *supra* note 3, Section 3.2.3.
- 93 See, e.g., <http://www.biomedexperts.com/> ; <http://www.researchgate.net/>. Indeed, the number of networks and strategic alliances has grown rapidly in recent years. See generally Glader, *supra* note 4 at 35.
- 94 See, e.g., http://www.almirall.com/webcorp2/cda/lmD_05.jsp.
- 95 See The Inter-Company Collaboration for AIDS Drug Development, at <http://www.ncbi.nlm.nih.gov/pubmed/11362548>.
- 96 See, e.g., the sharing of data on attempted treatments for Alzheimer’s disease, at http://www.fiercebiotech.com/story/big-pharma-share-failed-alzheimers-drugs-results/2010-06-11?utm_medium=nl&utm_source=internal.
- 97 See, e.g., malaria at <http://query.nytimes.com/gst/fullpage.html?res=9A01E6D81F3EF932A35750C0A9619C8B63&scp=3&sq=drug%20company%20partnerships&st=Search>; growth of public/private partnerships for diseases of poverty at <http://content.healthaffairs.org/cgi/content/full/24/4/1057>; lymphatic filariasis at <http://www.gsk.com/community/filariasis/index.htm>; and multi-drug resistant tuberculosis at <http://www.lillymdr-tb.com/>.
- 98 The list here is immense. See, e.g., GSK with Harvard Stem Cell Institute, <http://harvardscience.harvard.edu/foundations/articles/glaxosmithkline-and-harvard-stem-cell-institute-announce-major-collaboration-ag> ; and Pfizer with Washington University, http://media.pfizer.com/files/news/press_releases/2010/wu_collaboration_051710.pdf.
- 99 U.S. law, by virtue of the “rule of reason” (only “unreasonable” restraints are barred) did not lend itself to the exemption process. See, e.g., Bernard, *Private Damages Actions: A U.S. Perspective on Importing U.S. Damages Actions to the EU*, eCCP (October 2007).
- 100 A full discussion of EU legal structure is well beyond the scope of this article. The EU process was originally set up whereby almost any joint action by competitors could be viewed as a violation of the conspiracy in restraint of trade provision (now article 101), but the system had a process for requesting an “exemption” based on the net pro-competitive nature of the conduct at issue. The Commission was flooded with requests for exemptions, and came up with the idea of issuing Block

Exemptions (“BEs”) such that if your agreement fit within the four corners of the BE you were safe without having to make any individual request. The entire individual request process was abolished later, but the idea of the BE remains firmly embedded.

- 101 1984 R&D BE located at http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=1985&nu_doc=418; 2000 R&D BE located at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:304:0007:0012:EN:PDF>.
- 102 *Id.* at §3.
- 103 *Id.* at §4. There is a full discussion of this whole area in Glader, *supra* note 4 at 75-84, and the Commission lays out a concise analysis in the *2010 Horizontal Cooperation Guidelines* at §3.2; http://ec.europa.eu/competition/consultations/2010_horizontals/guidelines_en.pdf.
- 104 *2010 Draft Guidelines on Horizontal Cooperation*; available at http://ec.europa.eu/competition/consultations/2010_horizontals/guidelines_en.pdf. The language from section 51 of the 2001 Guidelines is the same.
- 105 http://ec.europa.eu/competition/consultations/2010_horizontals/guidelines_en.pdf at ¶141, example 2 (page 39). The definition of an R&D Pole is somewhat opaque. It perhaps can best be analogized to a research project in the broad sense, including the access to financial and human resources, patents, know-how, any other specialized assets, and the capacity to exploit the results. See, e.g., http://www.slaughterandmay.com/media/64578/the_eu_competition_rules_on_horizontal_agreements_apr_2010.pdf at §2.6. Another analogy would be the 1995 (U.S.) IP Guidelines, *supra* note 3 at §3.2.3.
- 106 Still, it would have been nice to have been given a safe harbor, say if there were three or more other R&D poles that would create a presumption (at least) that the deal should be cleared. See, e.g., Arnold & Porter Comments, at ¶5, available at http://ec.europa.eu/competition/consultations/2009_horizontal_agreements/arnold_porter_en.pdf.
- 107 While the rationale for the Commission’s actions is not on the public record as such, the lead lawyer for DG Competition, Luc Gyselen (now with Arnold & Porter in Brussels), has written it up in *Competition in Innovation: A Novel Concept – The Case Law on Pharmaceuticals*, ON THE MERITS—CURRENT ISSUES IN COMPETITION LAW AND POLICY 41-42 (L.Hancher & P. Lugar, eds) (2005).
- 108 *Id.* In a private note to me, Gyselen describes the case as being the only one in his recollection where the Commission looked solely on the impact of the joint venture on innovation to conclude that Article 101(1) applied.
- 109 See 2004 *EU Horizontal Merger Guidelines* at ¶9, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2004:031:0005:0018:EN:PDF>.
- 110 *Id.* at ¶38.
- 111 No divestiture of any human product was required in that case, so the discussion of the legal approaches was without prejudice to any result.
- 112 See, e.g., In re: Pfizer Inc., Case No. 001-0059 (2000), at <http://www.ftc.gov/os/caselist/c3957.shtm>, discussed earlier.
- 113 The well-known philosophical theory of Occam’s Razor counsels that where there are two approaches that lead to the same result, the simpler one is usually to be preferred. That certainly would seem to apply here. <http://www.xs4all.nl/~johanw/PhysFAQ/General/occam.html>.

- 114 See Carrier, *supra* note 4 at 417-419 (collecting sources); Gotts & Rapp, *supra* note 4 at 101.
- 115 The pressure to approve drugs to treat AIDS is a case in point, where a drug that looks possibly effective may well be fast tracked; see, e.g., Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 LEGISLATION & PUBLIC POL'Y 295 (2000), available at http://law.nyu.edu/ecm_dlv2/groups/public/@nyu_law_website__journals__journal_of_legislation_and_public_policy/documents/documents/ecm_pro_060626.pdf; see also the general FDA Statement on Priority Review, available at <http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm>.
- 116 Indeed that is the message of the 1995 IP Guidelines; IP Guidelines, *supra* note 3, §§ 2.0 and 2.1.
- 117 See Rosch Speech, *supra* note 1 at 13-14.
- 118 See <http://cat.inist.fr/?aModele=afficheN&cpsidt=1474187> for a brief overview.
- 119 See <http://www.thestreet.com/story/10781009/1/drug-firms-team-on-alzheimers.html>.
- 120 Rosch speech, *supra* note 1 at 21.
- 121 In that regard, the thesis here agrees with the observation of Timothy Muris in his article about bundled discounts: Many of the models and assumptions being applied in innovation market analysis not only lack empirical testing, but indeed are contradicted by the conduct and motivations in the real world. See Muris & Smith, *Antitrust and Bundled Discounts: An Experimental Analysis*, 75 ANTITRUST L.J. 399 (2008).