Thinking Economically About Commercial Success

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Economic experts frequently evaluate commercial success as a secondary consideration of the obviousness of a patented invention.[1] While other common economic inquiries are often based on widely recognized methodologies (e.g., the *Panduit* factors for lost profits, the *Georgia-Pacific* factors for reasonable royalties), experts often base analysis of commercial success on a layperson's notion of "success," without appreciation of its purpose. For example, an expert may conclude that a product is a commercial success because sales and profits are "large" or "substantial," appealing to preconceived notions of success in other contexts ("sales of $100 million a year? . . . sounds like a success to me!").

We should be wary of such simplistic approaches to evaluating commercial success, which often fail to ask a fundamental economic question: *success compared to what?* Just as one individual's success in life may differ from another's, commercial success for one product in a particular context may differ from commercial success for another product in another context. Improper analysis of commercial success can be particularly problematic in pharmaceuticals, for example, which often require billions of dollars in sales for economic incentives to have existed for others to bring the product to market sooner. Evaluations of commercial success without proper context (or, for some experts, without any context at all) are unhelpful to the role of commercial success in patent litigation.

Recent case law has clarified the purpose of commercial success and what it is intended to demonstrate. For example, the Federal Circuit stated in *Merck v. Teva* that commercial success is relevant "because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art."[2] This makes sense, from an economic perspective, because other parties would have economic incentives to commercialize obvious inventions if there were economic incentives to do so. However, based on our experience evaluating dozens of expert reports on commercial success, all too often experts fail to provide relevant context and/or tie any alleged success back to the fundamental purpose outlined by the courts.

This article summarizes challenges and shortcomings with common approaches to evaluating commercial success, and offers guidance for providing appropriate economic analysis. We draw upon numerous expert evaluations of commercial success, with a focus in pharmaceuticals and electronics, to provide practical insights on commercial success for both plaintiffs and defendants.

Overly Simplistic Analysis of Commercial Success

Overly simplistic evaluations of commercial success frequently fail to provide sufficient information and analysis to conclude that economic incentives existed to bring the product to market sooner. Such analysis often simply tabulates sales, profits, and market shares, followed by some grand conclusion on whether those constitute commercial success. Very little is said for whether sales are sufficient to compensate for the economic costs needed to develop the product and bring it to market. Experts often fail to compare sales and profits from the product in question to other comparable products in the industry, even though millions of dollars in one market might be successful in one industry and an utter failure in another.

In our experience, this kind of analysis is too often set forth as alleged evidence of commercial success. This overly simplistic approach to evaluating commercial success often misses the economic purpose of commercial success in informing on obviousness. Analyses rooted in a layperson's notion of success are not necessarily unscientific or false—rather, they simply fail to connect with the purpose of the commercial success established by the courts.

Over time, courts have clarified the purpose of commercial success in evaluating a patent's obviousness. Dating back to *Smith v. Goodyear Dental* (1876), the Supreme Court grappled with how to determine whether a new product was a legitimately novel invention.[3] The Court indicated what might be learned from one product displacing others previously used for the same purpose, establishing the relevance of a product's market performance, but provided no clear economic standard for what kind of displacement would be informative.[4] The Supreme Court later identified commercial success as a secondary consideration for nonobviousness in *Graham v. John Deere* (1966),[5] a role that was strengthened upon establishment of the Federal Circuit in 1982.[6] One scholar suggested that commercial success was transformed "from a tiebreaker to a virtual trump card."[7] Most recently, the Federal Circuit stated in *Merck v. Teva* (2005) (citing to *Graham v. John Deere*) that "[c]ommercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art."[8]

Merely reporting sales or market shares in a vacuum misses the point of a commercial success analysis as explained by the courts. Net sales or market shares in isolation tell us very little about whether market forces would have existed for other companies to have responded by bringing the product to market sooner. As one author noted: "For commercial success to be persuasive, a patentee must do more than show sales or market share data for her patented product. (Although, under some older cases, this was enough)."[9] Rather, commercial success should inform on whether sales and profits provide objective evidence on whether *material economic incentives* (i.e., "market forces") would have incentivized others to bring the product to market, had the invention been obvious. Other economists and scholars agree that this is, in essence, the fundamental purpose of commercial success analysis.[10] Said another way, ideas are brought to market when there is a profit opportunity, not merely when sales or market shares are "high" or "substantial" in some abstract sense.

Economic Analysis of Commercial Success

A better approach to evaluating commercial success focuses on factors that are economically relevant for its purpose. While each analysis will be unique and specific to the facts of the particular case, some principles can provide guidance to improve putting forth or rebutting evidence of commercial success. This section elaborates on several such factors: (1) comparisons to relevant benchmarks, (2) comparisons to commercialization costs, (3) evaluation of market shares, and (4) evaluation of the inferential limitations of any alleged commercial success.

Comparisons to Relevant Benchmarks

One useful measure in evaluating commercial success is a comparison of sales to relevant benchmarks in the industry—for example: average product sales, sales of competitors, and projections of potential sales. This provides guidance on what level of sales or revenues in the field are typical, sought, and expected, and would yield an economic profit for a particular industry at a particular point in time.

In the pharmaceutical industry, for example, economic literature provides context on the range of drug sales by drug type (e.g., cardiovascular, neurologic, etc.) and time period. For drugs launched from 1990 to 1994, anesthetic drugs earned $556 million over the product life cycle, on average, compared to more than $2 billion for anti-infective drugs and more than $3 billion for cardiovascular drugs.[11] Economic research examining drugs by decile (i.e., 1st decile from 90th percentile to 99th percentile, 2nd decile from 80th percentile to 89th percentile) often provides additional context for where a drug fits into the broader industry.[12] Notably, research indicates that only the top three deciles of drugs tend to be economically profitable, and that an average drug tends to yield close to break-even or even negative profits.[13] All else equal, it is unlikely that a drug with sales below an average drug would be a commercial success.[14]

All too often, experts assert that sales are "high" in some abstract sense (even with little or no profit), without evaluating what sales might have been expected or what sales have been earned by competitor products. By adding comparisons to the types of benchmarks described herein, sales can be evaluated in proper context and better inform whether material economic incentives for development existed.

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Comparisons to Commercialization Costs

Another useful but often overlooked measure in evaluating commercial success is a comparison to commercialization costs for a product. Properly evaluated, including economic costs associated with actual expenditures, costs of capital, risk, and uncertainties, comparisons to commercialization costs can provide information for whether sales and profits are sufficient to generate an economic return on investment—in other words, a material economic incentive for others to bring the product to market. For example, some economists argue that "commercial success could in principle be defined by a single criterion: Does the patented invention earn a positive net return (risk-adjusted) on invested capital after accounting for all relevant costs associated with developing and commercializing the patent as well as any alternatives available to the patent holder?"[15] Techniques such as net present value analysis can be helpful for comparing sales over time with costs associated with commercialization.

In the pharmaceutical industry, a number of authors have determined that the cost of bringing a new pharmaceutical product to market exceeds $1 billion (and more than $2 billion based on estimates for more recent products).[16] These costs include out-of-pocket expenses of development and clinical trials, the cost of capital over time, and the risk of nonapproval (in which case all expenditures would be wasted), all of which are expected and considered when evaluating products in the pharmaceutical industry.[17] If a drug product does not earn revenues and profits that sufficiently compensate pharmaceutical companies for significant economic costs in bringing a product to market, that product will tend not to be a commercial success, all else being equal.[18]

Despite the economic foundation and connection to material economic incentives, experts frequently fail to take into account the costs of development and commercialization when evaluating commercial success.[19] By adding comparisons to potential costs of commercialization described herein, sales and profits can be evaluated relative to the expense and investment required to bring the product to market, providing further evidence on material economic incentives for commercialization.

Evaluation of Market Shares

Market shares are a factor frequently considered by experts in evaluating commercial success, because they provide implicit comparisons to competitor products. However, the interpretation of market shares can be difficult. For example, experts are often pressed at deposition to define what market share would provide a global cutoff for a commercially successful product (e.g., "Is it 5 percent? 10 percent? 25 percent? 50 percent?"). The answer, because of how market shares are defined, is often: *it depends*.

For example, a 5 percent share of one market might be commercially successful, whereas a 20 percent share of another market might not be. The former market might be significant and commercialization costs may be low, whereas the second market might be smaller and commercialization costs may be high. As another example, a product may have a very high revenue share but a very low quantity share due to factors like patent protection of competitors (e.g., branded versus generic pharmaceuticals). Trying to define an absolute cutoff for what market share, in the abstract, denotes a commercial success is a futile exercise.[20] Experts often disagree about market definition—i.e., which products define competition and which do not—yet the market definition and market share are interrelated. It is the overall context, rather than a particular market share per se, that defines whether market shares are interpreted as persuasive evidence of commercial success.

Unlike the other economic factors described thus far, market shares are less directly connected to whether material economic incentives existed to bring the product to market sooner. Yet they can, at times, provide insight on the market opportunity for an invention and, in that sense, may inform on incentives to bring a product to market sooner when other information is less concrete.

Economic Relevance of Commercial Success

Finally, a thoughtful analysis of commercial success may consider whether any alleged success, if it exists, is relevant for evaluating the existence of material economic incentives to bring a product to market sooner. There are circumstances where even sales and profits that might normally be sufficient to generate economic interest in the product (e.g., a potential commercial opportunity) might not be informative on obviousness at the time of the invention because of other factors.

For example, the presence of blocking patents or regulatory exclusivity often limits the economic relevance of commercial success. In this case, incentives for development may only exist for the party with that exclusivity and not for the market more generally. In *Merck v. Teva*, the plaintiff argued that Fosamax, the patented product in question, was commercially successful.[21] The Federal Circuit agreed, but found that Merck's earlier patent (a so-called "blocking patent" that blocked others from commercializing a Fosamax product) limited the economic relevance of commercial success because other parties in the market could be blocked from bringing the product to market.[22] The court stated: "Because market entry by others was precluded on those bases, the inference of non-obviousness . . . from evidence of commercial success, is weak."[23]

As another example, there may be contemporaneous evidence around the time of the invention that shows a lack of commercial interest, even if the product later turns out to be commercially successful. In such a situation, sales and profits may provide limited evidence on whether material economic incentives existed to bring the product to market sooner, above and beyond the contemporaneous evidence already demonstrating this directly.

In summary, experts can often benefit from asking whether commercial success, even if it exists, is relevant in evaluating the existence of material economic incentives around the time of the invention and, in turn, in evaluating obviousness of a particular patent at issue.

Conclusion

While the purpose of commercial success has been established for some time, too often we see basic principles being misapplied, misunderstood, or not acknowledged at all. Evaluating "success" in a vacuum, without proper context or benchmarks

for comparison, can result in a flawed and misguided analysis. There is, of course, no single set of factors that are dispositive on commercial success in every situation, but providing additional context relating to the purpose of commercial success (i.e., whether sales and profits demonstrate material economic incentives existed to have brought the product to market sooner) appears to be a step in the right direction. Success, both in business and in life, requires an understanding and appreciation for what is meant to be achieved. ■

Endnotes

1. Commercial success is one of several secondary considerations intended to inform on whether a particular technology is obvious—i.e., whether it differs enough from prior art in order to qualify as a patentable invention—which are often evaluated when defendants challenge a patent's validity in patent litigation. Because obviousness is the most common basis for finding that a patent is invalid, commercial success can play an important role. For discussion and references, see Andrew Blair-Stanek, *Profits as Commercial Success*, 117 YALE L.J. 642, 646 (2008); and Rebecca S. Eisenberg, *Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA*, 19 BERKELEY TECH. L.J. 885, 885 (2004).

2. Merck & Co. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1376 (Fed. Cir. 2005).

3. Smith v. Goodyear Dental Vulcanite Co., 93 U.S. 486, 495 (1876).

4. *Id.* at 495–96, *cited in* Blair-Stanek, *supra* note 1, at 647.

5. Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966) ("Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.").

6. Blair-Stanek, *supra* note 1, at 647–48; *see Graham*, 383 U.S. at 11.

7. Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 803, 827 (1988).

8. Merck & Co. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1376 (Fed. Cir. 2005).

9. Merges, *supra* note 7, at 823.

10. Jesse David & Marion B. Stewart, *Commercial Success: Economic Principles Applied to Patent Litigation*, *in* ECONOMIC APPROACHES TO INTELLECTUAL PROPERTY: POLICY, LITIGATION, AND MANAGEMENT 196–99 (Gregory K. Leonard & Lauren J. Stiroh eds., 2005) ("A patented invention should be considered a commercial success if it can be shown to have earned, or can reasonably be expected to earn, a positive net return on invested capital after accounting for all relevant costs associated with development and commercialization . . . ."); Blair-Stanek, *supra* note 1, at 649 ("The potential for commercial success presumably provides incentives for others to try to perfect the invention, and the failure of others to do so suggests nonobviousness. Put most simply, the classical theory-based argument goes, 'if an invention is both obvious and lucrative, why wasn't it thought of earlier?'"); Rahul Guha et al., *The Economics of Commercial Success in Pharmaceutical Patent Litigation*, 1 LANDSLIDE, no. 5, May/June 2009, at 8 ("From an economic perspective, commercial success supports a conclusion of nonobviousness because it suggests that an economic incentive existed to produce the invention.").

11. Joseph DiMasi et al., *R&D Costs and Returns by Therapeutic Category*, 38 DRUG INFO. J. 211, 219 (2004).

12. Henry Grabowski et al., *Returns on Research and Development for 1990s New Drug Introductions*, 20 PHARMACOECONOMICS 11, 17, 22 (Supp. 3 2002).

13. *Id.* at 17, 23; Ernst R. Berndt et al., *Decline in Economic Returns from New Drugs Raises Questions about Sustaining Innovations*, 34 HEALTH AFF. 245, 245, 252 (2015).

14. Skeptics might question why so many unprofitable drugs are brought to market. Reasons may vary, of course, but one impactful factor is the uncertain process of clinical trials and FDA approval occurring over many years. Once a company incurs sunk costs of development and clinical trials, it may be worthwhile to proceed to the market, even if the product never recoups all of those sunk costs.

15. David & Stewart, *supra* note 10, at 196.

16. For sources and discussion, see Joseph DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016). For a variety of other sources and references over time, see JORGE MESTRE-FERRANDIZ ET AL., OFFICE OF HEALTH ECON., THE R&D COST OF A NEW MEDICINE 1–86 (2012); Joseph A. DiMasi & Henry G. Grabowski, *R&D Costs and Returns to New Drug Development: A Review of the Evidence*, *in* THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY 29 (Patricia M. Danzon & Sean Nicholson eds., 2010); Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 151 (2003); Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469, 477 (2007); and Grabowski et al., *supra* note 12.

17. *See* MESTRE-FERRANDIZ ET AL., *supra* note 16; DiMasi et al., *Innovation in the Pharmaceutical Industry*, *supra* note 16; DiMasi et al., *The Price of Innovation*, *supra* note 16; Grabowski et al., *supra* note 12.

18. Interestingly, some authors have argued that pharmaceutical products may be commercially successful even when they do not generate a positive return on investment, because there may still be some therapeutic value associated with their use. *See, e.g.*, Guha et al., *supra* note 10, at 11–12 n.10 ("[A] lack of positive return on capital investment should not necessarily undermine a conclusion of commercial success. A few 'blockbuster' drugs generate the majority of profits for the drug companies. That means the majority of smaller drugs may not be profitable in the sense of recouping all the costs of their discovery and development, even if they have proven therapeutic value."). However, products may be therapeutically valuable or desirable without being commercially successful and sufficient to provide incentives to bring products to market sooner.

19. While the costs of commercialization are often not available in historical records, either due to the passage of time or non-specific attribution of costs to a particular product, we have had success linking the facts and circumstances of a particular product to peer-reviewed published literature on commercialization costs, accounting for time of launch, therapeutic category, and the actual duration of clinical costs.

20. *See, e.g.*, David & Stewart, *supra* note 10, at 196 ("However, under certain circumstances, rapid sales growth and gains in market share will not *necessarily* reflect a profitable underlying invention.").

21. Merck & Co. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1376 (Fed. Cir. 2005).

22. *Id.* at 1376–77.

23. *Id.* at 1377.