

Unreliable Charts in Economic Consulting

“[A faulty chart] is vastly more effective, however, because it contains no adjectives or adverbs to spoil the illusion of objectivity, there’s nothing anyone can pin on you.”

- Darrell Huff, *How to Lie with Statistics* (1954)

A chart, to put it simply, conveys information. Nevertheless, a chart built on faulty analysis results in unreliable information. As an expert witness and economic consultant, I have come across a surprising number of unreliable charts that could have biased the trier of fact but-for proper analysis by an opposing expert.

In this article, I discuss some of the most common types of unreliable charts that I have encountered in my career. The examples herein are representative of different types of faulty analyses based on my experience working on dozens of antitrust and patent infringement matters. For context, the circumstances and analysis are simplified. None of the charts herein contain information (data or otherwise) from prior engagements. The opinions presented herein are my own and do not necessarily represent the views of Emerging Health LLC or its clients.

Absence of a Chart

Charts are commonly used to help the reader understand the underlying data or analysis. Consequently, the lack of a chart, when one is warranted, can be an indicator of faulty analysis.

Pay-for-Delay Example

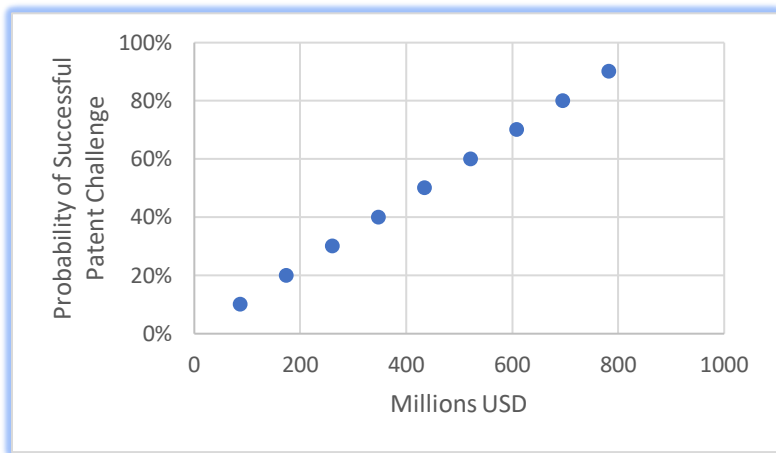
The Plaintiffs allege that, several years earlier, Co-Defendant Brand effectively paid Co-Defendant Generic a total of \$350 million to terminate a patent challenge that would have otherwise allowed Generic’s drug into the market under a favorable ruling. The Co-Defendants deny that the settlement included a large and unjustified payment. Consequently, the Plaintiffs allege that they incurred harm by paying higher prices as a result of this agreement. The Plaintiffs’ economic expert opines, in absolute terms, that Generic delayed its drug from the market in exchange for this payment.

The basis for this expert’s opinion is a financial model that utilizes numerous assumptions, particularly the probability that Generic would have succeeded in its patent challenge but-for the settlement. If Generic was certain to fail by both parties’ accounts, then any payment would have sufficed for Generic to terminate its patent challenge. However, as the perceived probability of success increased, Generic’s expectation to profit from the patent challenge would increase as well. Therefore, the minimum payment required by Generic to terminate the patent challenge is higher for higher probabilities of successfully challenging the patent.

In plotting the amount of requisite payment that corresponds to assorted probabilities of success, we can gauge the model’s sensitivity to those probabilities and the reasonableness of the expert’s opinion. As shown in the plot below, there is a positive relationship between the probability of

a successful patent challenge and the amount of payment sufficient for Generic to terminate the patent challenge.

The plot below reveals that a payment of \$350 million would only suffice to delay Generic’s drug if the perceived probability of a successful patent challenge was below 40%. However, if the trier of fact believes that the perceived probability of success exceeded 40% at the time of the settlement between the Co-defendants, the expert’s opinion in this matter is moot. A chart that examined the sensitivity of the model to the assumptions relied upon proved helpful in identifying the expert’s faulty opinion.

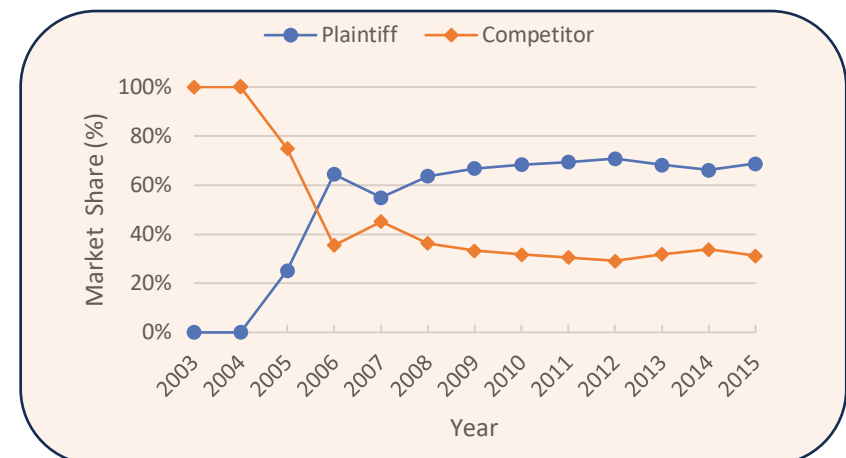


Unsuitable Unit

Charts are commonly used to compare assorted data, such as sales of similar products and competing products. Consequently, an unsuitable unit of comparison between products can be an indicator of faulty analysis.

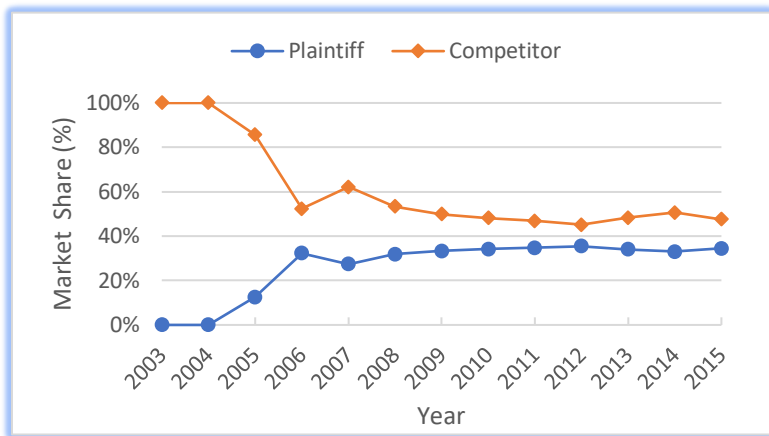
Paragraph IV Example

The Plaintiff alleges that the Defendant has infringed the Plaintiff’s patents. In response, the Defendant alleges that the Plaintiff’s patents are obvious, therefore invalid. The Plaintiff’s economic expert opines that the commercial success of the Plaintiff’s drug, which embodies the patents, is secondary indicia of non-obviousness of the patents. In arriving at this opinion, the Plaintiff’s economic expert compares the market share by using unit sales of the Plaintiff’s drug to another drug with the same FDA-approved indication and dosage form as shown in the chart below.



Indeed, the above chart shows that the market share of the Plaintiff’s drug overtakes the market share of the competitor’s drug as measured by unit sales. However, the use of unit sales as the basis of comparison is inappropriate and results in faulty analysis. Although both drugs have the same FDA-approved indication and dosage form, the Plaintiff’s drug is administered daily while the competitor’s drug is administered every other day according to the FDA approved prescription label. A proper analysis will use a unit of comparison that is both unbiased and common, such as the number of patients being treated. In this particular case, every unit sale results in twice as many treated patients for the competitor’s drug than the Plaintiff’s drug.

Consequently, appropriate analysis of market share based on the number of patients treated reveals that the Plaintiff’s drug never surpassed that of the Competitor’s drug. Analysis based on an unbiased and common unit of comparison provides greater insight into the market shares of competing drugs.

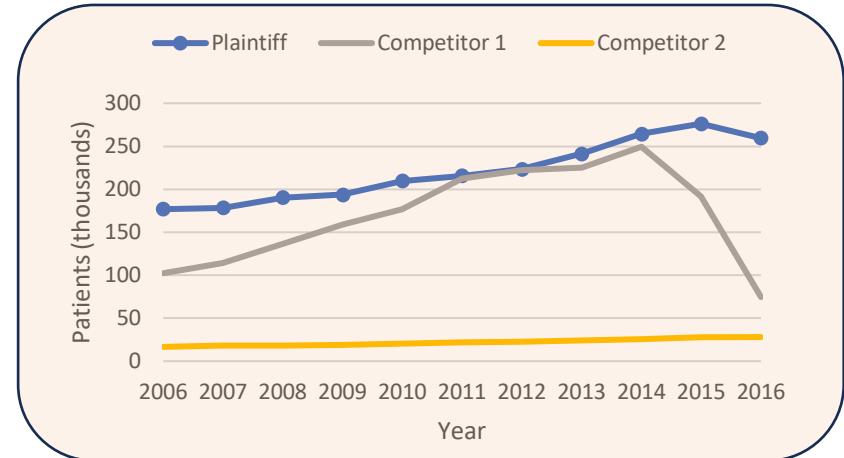


Incomplete Data

Another indicator of faulty analysis when comparing data, such as sales of similar products and competing products, is to use data that is incomplete.

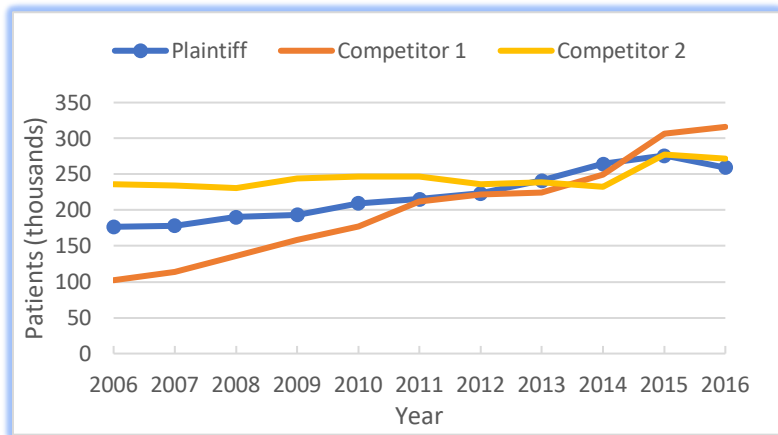
Paragraph IV Example

The Plaintiff alleges that the Defendant has infringed the Plaintiff’s patents. In response, the Defendant alleges that the Plaintiff’s patents are obvious, therefore invalid. The Plaintiff’s economic expert opines that the commercial success of the Plaintiff’s drug, which embodies the patents, is secondary indicia of non-obviousness of the patents. To formulate her opinion, the Plaintiff’s economic expert relied upon analysis indicating that the number of patients treated with the Plaintiff’s drug exceeded that of all other branded drugs with the same FDA-approved indication as shown in the chart below.



Indeed, the above chart shows that the number of patients treated with the Plaintiff's drug equaled or exceeded that of all other branded competitors. However, this chart does not accurately depict competition in the market since it does not account for competition from generic drugs. Competitor 1 encountered generic entry in 2015 resulting in the immediate generic erosion of Competitor 1 sales. While the drop in sales of Competitor's drug 1 is illustrated in the chart, the increase in sales of the generic version is not. Moreover, Competitor 2 encountered generic entry well before 2006 yet the chart does not account for any generic sales of that product. A more appropriate analysis will compare the market share of the Plaintiff's drug to all other branded and non-branded drugs with the same FDA-approved indication as shown in the chart below.

Consequently, the chart illustrates that competing drugs treated more patients than the Plaintiff's drug nearly every year.

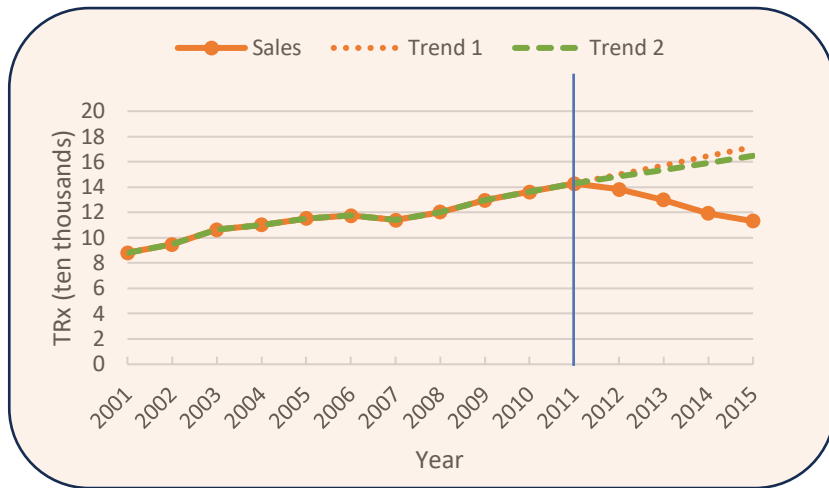


Confirmation Bias

Analysis that is limited to the data that supports a working hypothesis can bias the analysis. While some analyses can appear simple on the surface, deeper analyses can either prove or disprove that initial appearance.

Black-Box Warning Example

Plaintiff alleges that Defendant sold a drug it knew to be less effective for patients with a specific genetic variance for several years before notifying the FDA and physicians. Plaintiff further alleges that, as a third-party payor for the drug-at-issue, it suffered financial harm and is requesting reimbursement for the prescriptions filled by its members. The Defendant purports that a black box warning was added to the prescription label upon learning of the concern. Moreover, the Defendant argues that there is no evidence the issue is material to the prescribing decision of physicians. The Plaintiff's economic expert opines that the issue is materially relevant to prescribers. To inform her opinion, the expert compares the number of prescriptions issued after the black-box warning was finalized in 2011 to the expert's projected trends in sales. The first trend is based on sales between 2007 and 2011 and the second trend is based on sales between 2001 and 2011.



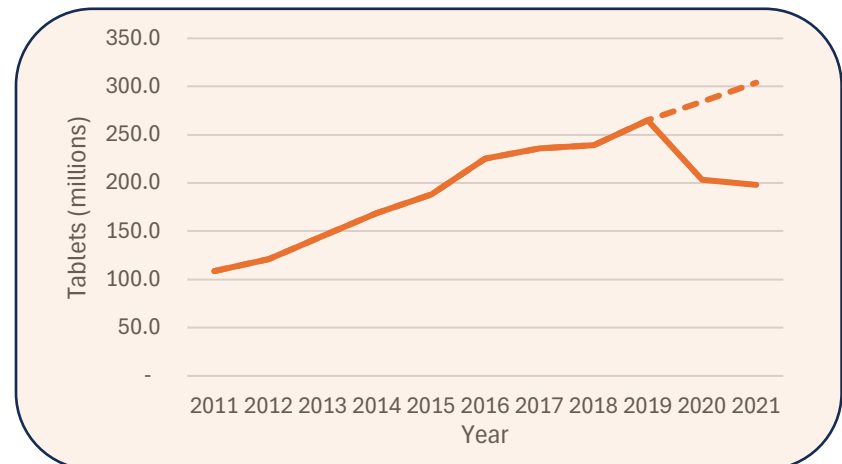
Indeed, the projected trends are above actual sales for the period after the black-box warning was finalized in 2011. However, the expert does not provide any supporting evidence for the projected trends. Generally, an underlying assumption of relying on past trends for projections is that no forthcoming events will undermine use of the past trend. However, this assumption requires supporting analysis. The Plaintiff’s expert ignores two facts that weaken this assumption. First, a more efficacious drug with a similar indication was approved in Q4 2012 which could explain the sales erosion of the drug-at-issue. Second, the black-box warning was first added to the prescription label in 2009 and then amended in 2011. The Plaintiff’s expert does not explain why sales did not decline after the black-box warning was added in 2009 but did decline after the amendment in 2011.

Unsupported Analysis

A simple chart can effectively deliver the results of complex analysis. However, simplicity should not come at the cost of accurate analysis.

Breach of Contract Example

Plaintiff alleges that the Defendant breached a contract to manufacture requested quantities of the Plaintiff’s drug. The Plaintiff’s economic expert opines that but-for the breach, the Plaintiff would have sold higher quantities as shown by the dashed line below. The expert’s 2020-2021 projections are based on the trend in sales leading up to 2020. The expert also claims that the damages incurred by the Plaintiff amount to the additional profits that the Plaintiff would have sold but-for the breach.

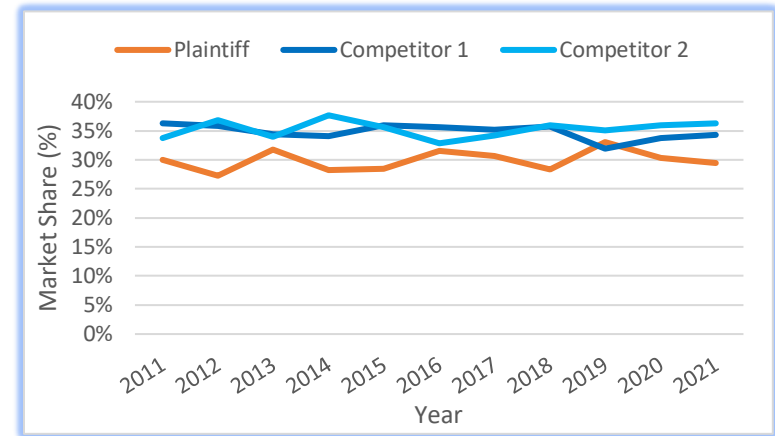


The chart shows that there is a decline in sales after 2019. However, the expert fails to disclose that she considered the potential effect of an API

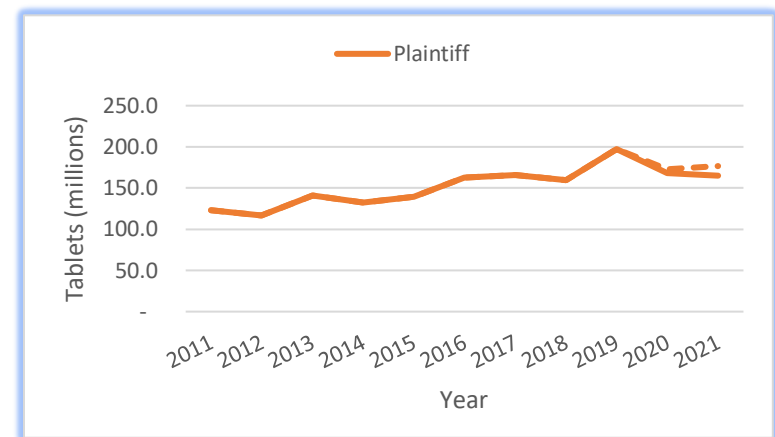
shortage in 2020-2021 that impacted sales across all competitors. As shown in the chart below, total market sales stabilized near 2019 levels.



Does this mean that the expert’s projections are wrong? Not necessarily. The Plaintiff’s sales could have increased as projected by the expert but only if it had taken market share from competitors during the shortage period. As shown in the chart below, the market shares of all three competitors remained relatively stable from 2011 to 2021.



Moreover, there is no evidence that any of the competitors’ market strategies were expected to change for 2020-2021. Consequently, there is no evidence to indicate that market shares would have differed for the projected period in comparison to the decade prior. Projections based on persistent market shares indicate that damages would be substantially lower than projected by the Plaintiff’s expert.



About Us



Dr. Omar Robles is Managing Partner at Emerging Health LLC. Dr. Robles has consulted on numerous commercial litigations concerning prescription pharmaceuticals, medical devices, and dietary supplements. His engagements have concerned antitrust claims and intellectual property matters litigated in US federal and state courts, the US Patent Trial and Appeal Board, and Canadian courts.

Dr. Robles has previously held appointments at Harvard University, University of California-Berkeley, Georgetown University and University of Maryland-College Park. He has published in peer-reviewed journals such as *JAMA*, the *American Economic Journal: Applied Economics* and the *Journal of Health Economics*. Dr. Robles routinely publishes articles in health policy and life sciences news sources such as *Health Affairs Forefront* and *Law360* as a life sciences expert.

Emerging Health LLC is an economic and clinical consultancy delivering solutions to complex business and legal challenges in life sciences based on our economic and strategic expertise.