

"Commercial Success" in Pharmaceutical Patent Litigation, and Cross-Examination of the Patent Owner's Economist

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A defendant accused of infringing a patent may challenge the validity of the patent, among other ways, on the grounds of obviousness of the claimed invention. Obviousness must be proven by clear and convincing evidence.

Obviousness of an invention is established if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the pertinent art. An obviousness analysis includes the following factual determinations: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; (3) the level of ordinary skill in the pertinent art; and (4) any secondary considerations of nonobviousness, such as commercial success of the invention, satisfaction of a long-felt but unsolved need by the invention, and failures of others attempting to solve the problem addressed by the invention. *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734 (2007).

SECONDARY CONSIDERATIONS

Secondary considerations of nonobviousness serve to protect against the impermissible use of hindsight in determining whether combinations of, or adjustments to, prior art references, would have been obvious to a person of ordinary skill in the art. *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1377 (Fed. Cir. 2007).

In the post-KSR world, secondary considerations may have a heightened importance. Secondary considerations focus on real-world, factual evidence concerning the invention in question, so as to "replac[e] judicial hindsight with objective determination as of the time of the invention." *PharmaStem*, 491 F.3d at 1377.

The courts have identified at least seven secondary considerations: (1) the commercial success of the invention; (2) a long-felt but unsolved need; (3) failure of others to produce the invention; (4) surprising or unexpected results (or properties) of the invention; (5) licenses showing industry respect for the invention; (6) skepticism of skilled artisans before the invention; and (7) copying by others. The weight accorded to each of the secondary considerations depends on the nature of the case and which of the secondary considerations are at issue.

When deciding the issue of obviousness, the court must consider any secondary considerations. *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 667 (Fed. Cir. 2000). However, evidence of secondary considerations is not to be given substantial weight if it has no nexus to the merits of the claimed invention. *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1327 (Fed. Cir. 2008).

A patentee must establish a nexus between the evidence presented and the merits of the claimed invention, *i.e.*, the patentee bears the burden of demonstrating "a legally and factually sufficient connection" between the evidence of the patented invention to demonstrate that the evidence offered does, in fact, corroborate the invention's non-obviousness. *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994). Even when present, however, the evidence of secondary considerations still must be of sufficient weight to override a determination of obviousness based on primary considerations where there is strong evidence of obviousness. *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 719 (Fed. Cir. 1991).

BURDENS RE COMMERCIAL SUCCESS

The patent owner bears the initial burden of proving that there is a nexus between the claimed invention and the commercial success. *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311-12 (Fed.Cir. 2006). When a patent owner demonstrates that there are significant sales in a relevant market and the successful product is disclosed and claimed in the patent, a presumption arises that there is a nexus. *Ormco Corp.*, 463 F.3d at 1312; *J.T. Eaton & Co., Inc. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997).

After the patent owner satisfies the initial burden, the burden shifts to the party asserting obviousness to present evidence to rebut the presumed nexus by demonstrating that the commercial success is instead due to other factors, such as marketing or superior workmanship. *J.T. Eaton*, 106 F.3d at 1571. Evidence must be used to rebut the presumed nexus, mere argument cannot be used. *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1130 (Fed.Cir. 2000).

COMMERCIAL SUCCESS IN ANDA LITIGATION

Pharmaceutical patent infringement cases involving Abbreviated New Drug Applications (ANDAs) which include Paragraph IV certifications for brand name drugs listed in the Orange Book often involve consideration of commercial success. Some commentators have incorrectly concluded that commercial success is not a factor in ANDA cases based on the ruling in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005), *reh'g denied* 405 F.3d 1338, *cert. denied*, 126 S.Ct. 488 (2005). However, that ruling is limited to cases having similar facts involving a "blocking patent" issued before the patent-in-suit, which blocking patent, combined with certain FDA exclusivities, excluded others from competing in the subject market. *Pfizer v. Teva Pharmaceuticals USA, Inc.*, 460 F.Supp.2d 650, 654 (D. NJ. 2006). Further, the court in *Merck v. Teva* concluded that the inference of non-obviousness from evidence of commercial success was "weak" (not that it was non-existent).

Since the facts in many ANDA cases are distinguishable from the facts in *Merck v. Teva*, commercial success often is an issue in ANDA cases. Typically, commercial success, failure of others, and long-felt but

unsolved need are areas of dispute in these cases.

In ANDA cases, as in other types of patent infringement cases, there must be a “nexus” between a claimed invention and the “commercial success” of a product embodying that invention for the commercial success to have probative value (in the obviousness determination). The brand company’s initial burden is very light in that it only needs to show that there have been sales of the product in a relevant market. At that point, there is a *presumption* that those sales are due to the claimed features of the invention (*i.e.*, that there is a nexus). The burden then shifts to the challenger (generic company) to show that the sales are due to other factors, such as marketing, advertising, *etc.*

The parties usually engage experts to opine on commercial success. Such experts often are economists, although other professionals may be experts in this area, such as accountants, marketing professionals, and product development professionals.

Economists analyze a number of factors to determine whether a product is, in fact, commercially successful. Four such factors are discussed below. See Mohan Rao, “Economic Analysis of Commercial Success as a Secondary Consideration,” Working Paper, LECC, 2009.

First, a commercially successful product is generally differentiated in the marketplace as a result of its patented features. In the pharmaceutical industry, this differentiation is typically due to differences in efficacy and/or side effect profiles. Therapeutic differentiation may be established through clinical studies that compare products on their efficacy and side effect profiles, or through physician surveys.

Second, markets react to innovative products. Such market reaction should be reflected in significant sales and market share if a product is a “commercial success.” Innovative products also tend to expand the market demand for such products. Thus, if a brand drug is an “innovative product,” that factor may weigh in favor of the drug being a commercial success.

Third, the sales of a product that is a “commercial success” should not be due to advertising and promotion, but to the patented features of the product. Economists recognize that producers promote and advertise their products to inform consumers of product features and to differentiate the products in the marketplace. This is especially so for pharmaceutical products

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where physicians need to be educated on the efficacy and side effect profiles of individual products. Pharmaceutical companies compete through “detailing” to physicians and through other promotion to differentiate their products in the marketplace. They often increase such efforts around new product launches.

A key issue for an analysis of commercial success is whether advertising and marketing – rather than the patented features of the product – are the main drivers of sales. This may be evaluated by measuring the influence of advertising and marketing on sales. If product sales are driven by advertising and marketing, one would expect sales to increase with increasing advertising and marketing efforts and decrease when advertising and marketing efforts are reduced. Another way to evaluate the effect of advertising and marketing on sales is to compare ratios of advertising and marketing to sales across competing products in the same therapeutic class.

Fourth, a “commercially successful” product should typically command a price premium, as consumers are willing to pay extra for the specific benefits offered by the product. Pricing for pharmaceutical products is generally based on “economic value added” to the consumer. Products that deliver higher efficacy, better side effect profile, or easier formulations, compared to existing therapeutic alternatives, arguably should support a higher price.

CROSS EXAMINING THE ECONOMIST

Defense counsel responsible for cross-examining an economist hired by a brand company to opine on commercial success will plan and prepare for that cross-examination somewhat differently in each case depending on the facts of the case, the theme of the defense, the overall case

strategy, *etc.* However, the following goals or objectives are likely to be included in the cross-examination in many cases:

- i. Putting into question the economist’s credibility, qualifications, experience, *etc.*
- ii. Discrediting the economist’s expert opinions, methodologies, underlying assumptions, and quality of work
- iii. Developing support for your own legal theory and assumptions by using the opposing economist’s expert report, calculations, deposition testimony, *etc.*
- iv. Demonstrating a lack of nexus between sales and the patented features of the product, and/or that the sales are due to other factors (*e.g.*, marketing, advertising, *etc.*)

In addition to including particular questions applicable to ANDA cases and specific questions applicable to the particular case at trial, the cross-examination should include the types of questions typically included in the cross-examination of expert witnesses in most other types of commercial litigation. A general outline of points to be considered in preparing for and conducting cross-examination of an economist follows.

I. GENERAL CONSIDERATIONS

- A. The Purpose of the Cross-Examination
 1. Is cross-examination necessary? Has the adverse expert’s testimony hurt you? If not, do not cross-examine.
 2. What is the cross-examination intended to achieve?
 - a. full attack on the adverse expert witness, or
 - b. poke holes in the testimony of the adverse expert witness.
- B. Plan the Cross-Examination

1. Organize your material in an outline that can be used easily during the cross-examination.
 2. Outline the topics and individual points to be covered in a preferred order.
 3. Plan to cover a limited number of topics thoroughly and effectively, rather than scattering your attack over a large number of topics ineffectively.
 4. Plan to begin and end on strong points; save the more contentious points for the middle of the cross-examination.
- C. Goals/Objectives of the Cross-Examination
1. Put into question the credibility of the adverse expert witness.
 2. Demonstrate bias.
 3. Demonstrate lack of experience and/or training in the subject matter at issue.
 4. Obtain concessions and admissions.
 5. Identify the areas where the adverse expert agrees with your expert.
 6. Structure the cross-examination with an overall theme such that the cross-examination dovetails with your expert's opinions and testimony.
- D. Scope of the Cross-Examination
1. Qualifications – create skepticism about the testimony of the adverse expert witness.
 2. Bias and/or interest
 3. Prior inconsistent testimony and/or publications
 4. Lack of knowledge of the subject matter
 5. Lack of adequate basis for opinions
 6. Different opinions result from changes in the adverse expert's assumptions.
- E. Basic Rules of Cross-Examination
1. Ask leading questions.
 2. Ask short questions.
 3. Control the witness.
 4. Set the tempo.
 5. Don't ask "why" or ask for explanations.
 6. Keep it simple and short.
 7. Hit only the most important areas.

II. METHODS OF ATTACK

A. Qualifications

1. The adverse expert witness lacks training/education related to the topics of the testimony.
 2. The adverse expert witness lacks experience in the fields involved in the testimony.
 3. The adverse expert witness has been criticized by another court(s), or has failed to be qualified to testify as an expert by another court(s).
- B. Bias
1. Does the adverse expert testify so often that he is a "professional witness"?
 2. Does the adverse expert testify for only one party?
 3. Is the adverse expert's fee significantly higher than the fees of comparable experts?
 4. Establish the nature and extent to which the adverse expert has a relationship with the party or attorney for whom he is testifying.
 5. Identify any financial stake which the adverse expert may have in the outcome of the case.
- C. Prior Inconsistent Testimony or Publications
1. Is the adverse expert's testimony contradicted by his writings or prior testimony?
 2. If so, recommit the expert to his prior inconsistent testimony or statements.
 3. Confront the expert with the inconsistency.
- D. Lack of Adequate Basis for Opinions
1. Fed.R.Evid. 705: disclosure of facts or data underling the expert's opinions.
 2. Do the adverse expert's opinions change if the facts change?
- E. Assumptions and Impact of Changes in Assumptions
1. Assumptions underlying the adverse expert's opinions are prime areas for cross-examination.
 2. Emphasize those assumptions which are most vulnerable and/or have the most dramatic effect on the adverse expert's conclusions.
 3. Ask hypothetical questions which demonstrate the impact of changing the assumptions on the adverse expert's conclusions.
 4. Show inconsistencies in the basis of the adverse expert's assumptions as being liberal in some areas (e.g., sales revenue) but conservative in others (e.g., the discount rate).

5. Ask your expert to assist by identifying sensitive assumptions, checking calculations, pointing out inconsistencies, etc.
 6. Use visual aids showing the results of changing assumptions.
- F. Methodology
1. Show gaps in the adverse expert's procedures, such as what he failed to take into account.
 2. Highlight significant errors or inaccuracies in the adverse expert's calculations, illustrations, etc.
 3. Attack the appropriateness of the adverse expert's methodology.
 4. Has the adverse expert failed to consider relevant documents?
 5. Has the adverse expert applied the methodologies incorrectly?
 6. Show that the adverse expert failed to consider all of the relevant data, key documents or deposition testimony.
 7. Demonstrate that the adverse expert's work is sloppy or incomplete.
 8. Show that the adverse expert failed to consider independent data from outside sources.
- ### III. POTENTIAL PROBLEMS TO AVOID
- A. Avoid Giving the Adverse Expert Opportunities to Repeat or Reinforce Points Made During Their Direct Testimony.
1. Do not ask open-ended questions.
 - a. Maintain control of the adverse expert witness.
 - b. Do not ask questions which will elicit a repeat of the adverse expert's direct testimony.
 - c. Do not provide the adverse expert opportunities to explain their answers or give speeches in the form of long narratives.
- B. Avoid Asking "One Question Too Many."
- C. Don't Ask "Why" or Ask for an Explanation.
- D. Don't End Your Cross-Examination on a Low Note. **IPT**