

# Expansion of the blocking-patent doctrine

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In 2005 the U.S. Court of Appeals for the Federal Circuit first articulated the blocking-patent doctrine in *Merck & Co. v. Teva Pharmaceuticals USA Inc.*, 395 F.3d 1364 (Fed. Cir. 2005), or *Merck I*.

The Federal Circuit said that under the doctrine courts may reduce the weight given to evidence of commercial success where an earlier patent blocked market entry by others.

The appellate court later explained in *Acorda Therapeutics Inc. v. Roxane Laboratories Inc.*, 903 F.3d 1310 (Fed. Cir. 2018), that a patent is a blocking patent “where the practice of a later invention would infringe the earlier patent.”

The rationale behind the doctrine was that where others are legally barred from commercializing a purportedly obvious idea due to a preexisting patent, the court may conclude that the inference of nonobviousness from evidence of commercial success is weak.

After establishing the doctrine in *Merck I*, the Federal Circuit initially invoked it only with respect to commercial success.

With *Acorda* and later cases, however, the Federal Circuit has expanded the doctrine beyond commercial success, applying it in evaluating other objective indicia of nonobviousness — long-felt need and the failure of others.

## ORIGINS OF BLOCKING-PATENT DOCTRINE

*Merck I* involved a patent covering a method for treating and preventing osteoporosis through less-than-daily administration of bisphosphonate compounds.

The district court found the patent valid,<sup>1</sup> but the Federal Circuit reversed.

The Federal Circuit concluded, in part, that the district court erred in weighing the objective indicia of nonobviousness.<sup>2</sup>

While the district court correctly found that Merck demonstrated commercial success, the Federal Circuit held that commercial success in this case had minimal probative value on the issue of obviousness.

Commercial success is relevant to the question of obviousness because the law presumes someone would have successfully brought an idea to market sooner in response to market forces if the idea was obvious to people of ordinary skill in the art.<sup>3</sup>

Therefore, the law considers two factors to be probative of whether or not an invention would have been obvious: evidence of (1) commercial success, and (2) a causal nexus between the invention and commercial success of a product embodying it.<sup>4</sup>

The Federal Circuit in *Merck I* explained that the district court’s finding of commercial success should be given only minimal weight because Merck had both (1) a preexisting patent covering the administration of alendronate sodium (a bisphosphonate) to treat osteoporosis, and (2) exclusive marketing rights granted by the Food and Drug Administration.

“Because market entry by others was precluded on those bases, the inference of nonobviousness ... from evidence of commercial success ... is weak.”<sup>5</sup>

In the years after the Federal Circuit’s decision in *Merck I*, the court invoked the blocking-patent doctrine a handful of times — but solely with respect to commercial success.

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## The expansion of the blocking-patent doctrine is difficult to reconcile with the obviousness standard established by the U.S. Supreme Court.

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For instance, in *Galderma Laboratories LP v. Tolmar Inc.*, 737 F.3d 731 (Fed. Cir. 2013), the Federal Circuit applied the blocking-patent doctrine to conclude that the district court erred in relying on commercial success to support a finding of nonobviousness.

The majority found that the evidence of commercial success supporting the nonobviousness of a formulation patent had limited value because the patentee held earlier patents covering the active compounds, which “blocked the market entry” of products containing the patented formulation until their expiration.<sup>6</sup>

And in *Merck Sharp & Dohme Corp. v. Hospira Inc.*, 874 F.3d 724 (Fed. Cir. 2017), or *Merck II*, the Federal Circuit affirmed a district court’s application of the blocking-patent doctrine to discount what it found to be persuasive objective evidence when weighing the obviousness factors.<sup>7</sup>

However, the majority in *Merck II* cautioned that evidence of commercial success should not be discounted simply because of

the existence of another patent owned or exclusively licensed by the patentee.<sup>8</sup>

In fact, the majority emphasized that the patent holder's FDA marketing exclusivity in *Merck I* was fundamental to the application of the blocking-patent doctrine.<sup>9</sup>

Less than one year after *Merck II*, the Federal Circuit expanded the blocking-patent doctrine beyond commercial success, in a case with no prior FDA-marketing exclusivity, applying it in the evaluation of other objective indicia of nonobviousness.

### EXPANSION OF THE DOCTRINE

The *Acorda* case involved patents covering Acorda's Ampyra, 20 mg 4-aminopyridine sustained-release tablets for twice-daily oral administration, to improve walking in patients with multiple sclerosis.

The earliest of the patents was referred to as "the Elan patent" because it was originally assigned to Elan Corp.

Acorda obtained an exclusive license to the Elan patent, which claimed methods of treating patients having certain conditions, including MS, by administering a drug containing a sustained-release formulation of any of a group of agents, one of which was 4-AP.

The other patents were referred to as "the Acorda patents." They further specified that 4-AP must be administered in a 10 mg dose twice a day for a treatment period of at least two weeks to achieve 4-AP serum levels of 15-35 ng/ml and thus improve walking in patients with MS.

After a bench trial, the district court ruled that the Elan patent was not obvious but the Acorda patents were.<sup>10</sup>

With respect to objective indicia, the district court found both that Ampyra was a commercial success and that it satisfied a long-felt but unmet need for a treatment of walking in patients with MS. Acorda also presented evidence that at least two other companies had tried but failed to develop a therapy to improve walking in MS patients.

But the court found the objective evidence to be of little probative value to the obviousness inquiry because the earlier Elan patent blocked competitors from practicing the Acorda patents.<sup>11</sup>

This was the first time that a court applied the blocking-patent doctrine to discount evidence of objective indicia other than commercial success.

On appeal, the Federal Circuit affirmed the district court's conclusion that the asserted claims of the Acorda patents were invalid as obvious.

The majority concluded that "the district court did not err in viewing the Elan patent ... as evidence that discounted the weight of Acorda's evidence of commercial success, failure of others and long-felt but unmet need."<sup>12</sup>

Acorda's petition for rehearing en banc and its petition for a writ of certiorari were both denied.

### THE BLOCKING-PATENT DOCTRINE AND THE OBVIOUSNESS STANDARD

The expansion of the blocking-patent doctrine is difficult to reconcile with the obviousness standard established by the U.S. Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

The Court in *Graham* set forth a four-factor test that courts must consider in evaluating obviousness.

The factors are:

- (1) "the scope and content of the prior art,"
- (2) "differences between the prior art and the claims at issue,"
- (3) the "level of ordinary skill in the pertinent art," and
- (4) objective "indicia" of nonobviousness.<sup>13</sup>

Courts have repeatedly recognized the importance of objective indicia in the obviousness analysis. The Court in *Graham* emphasized that objective indicia perform an essential function in the obviousness inquiry because they "guard against slipping into use of hindsight."<sup>14</sup>

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Commercial success is relevant because the law assumes that if an idea was obvious, then it would have been brought to market sooner.

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Evidence of objective indicia of nonobviousness "may often establish that an invention appearing to have been obvious in light of prior art was not."<sup>15</sup>

In fact, the Federal Circuit has noted that "objective indicia may often be the most probative and cogent evidence of nonobviousness in the record."<sup>16</sup>

And perhaps most important, the Federal Circuit has consistently held that district courts *must* consider all four *Graham* factors, and that it is legal error to reach a conclusion on obviousness before all four factors are considered.<sup>17</sup>

Yet while both the Supreme Court and Federal Circuit have highlighted the significance of objective indicia, the Federal Circuit's expansion of the blocking-patent doctrine substantially discounts the role objective indicia play in the obviousness analysis.

This expansion is potentially at odds with the obviousness analysis required by *Graham*.

The original articulation of the blocking-patent doctrine was limited to commercial success because the inference of

nonobviousness due to commercial success is supposedly weakened if others were precluded from entering the market by a blocking patent.<sup>18</sup>

Indeed, commercial success is relevant because the law assumes that if an idea was obvious, then it would have been brought to market sooner in response to market forces.

Even as applied solely to commercial success, the blocking-patent doctrine has been subject to debate.

Three Federal Circuit judges dissented from the majority's decision to deny a petition for rehearing en banc in *Merck I*.<sup>19</sup>

One of those dissenters, Judge Alan D. Lourie, explained: "Commercial success is a fact question, and ... [i]t is not negated by any ability of others to test various formulations because of the existence of another patent. Success is success."

But the Federal Circuit's recent expansion of the blocking-patent doctrine increases the potential for district courts to disregard objective indicia altogether whenever a prior blocking patent exists. Further, long-felt need and failure of others are not necessarily impacted by the existence of a blocking patent.

The Federal Circuit has ruled that evidence of long-felt need and failure of others is probative of nonobviousness because it "demonstrates both that a demand existed for the patented invention, and that others tried but failed to satisfy that demand."<sup>20</sup>

Courts should be able to find evidence of preexisting market demand and others' failed attempts to satisfy that demand despite earlier blocking patents. In fact, courts can find evidence of others' failure based on different compounds or processes than those disclosed by the patent at issue as long as they shared a "common goal."<sup>21</sup>

While the existence of blocking patents is relevant, courts should be cautious not to simply discount evidence of objective indicia due to an earlier patent.

Instead, courts should consider the specific facts surrounding each of the objective indicia presented and the alleged blocking patent's impact with respect to each of them.

### BURDEN OF PROOF

Another concern is that courts may improperly shift the burden of proof when evaluating blocking patents.

Pursuant to Section 282 of the Patent Act, 35 U.S.C.A. § 282, patents enjoy a presumption of validity, and a party seeking to establish otherwise bears the burden of proof.

While the patent holder bears the burden of producing evidence of objective indicia of nonobviousness, the ultimate burden of proving obviousness at all times remains with the defendant.<sup>22</sup>

As explained in a dissent to the majority's opinion in *Merck II*, "some Federal Circuit decisions appear to have converted three of the four *Graham* factors into a self-standing 'prima facie' case, whereby the objective considerations must achieve rebuttal weight."<sup>23</sup>

This approach can distort the burden of proof, especially when courts are inclined to discount evidence of objective indicia when there is a blocking patent.

Therefore, courts should ensure that, when considering blocking patents and their impact on the obviousness analysis, the burden of proving invalidity is not improperly shifted to the patent holder.

### IMPACT ON INNOVATION

The expansion of the blocking-patent doctrine also has the potential to discourage innovation. And while the doctrine has its origins in cases involving pharmaceuticals, it appears to be applicable to any technology.<sup>24</sup>

Patent protection helps provide economic incentive for individuals and companies to undertake expensive research and development, which can have long time horizons and a high degree of risk. But the doctrine may be used against any improvement patent as long as a challenger can point to an earlier blocking patent.

Indeed, Judge Lourie warned that the blocking-patent doctrine is "especially unsound" in the context of improvement patents because it essentially renders objective indicia for such patents irrelevant when a prior patent covers the basic invention.<sup>25</sup>

As a result, companies may be less likely to pursue continued research in a particular area if they think that their inventions may have a higher likelihood of being invalidated.

### DOCTRINE'S EXPANSION

Objective indicia of nonobviousness play a fundamental role in the obviousness inquiry and must be considered in every case where they are present.

Blocking patents may be relevant in analyzing objective indicia, but the expansion of the blocking-patent doctrine may cause courts to disregard crucial objective evidence altogether or to shift the burden to the patentee.

The doctrine's expansion may lead to an increase in its use. It remains to be seen how the courts, the U.S. Patent and Trademark Office and the Patent Trial and Appeal Board will apply the expanded blocking-patent doctrine going forward, but it will be important to ensure that it is applied carefully and that tribunals applying it consider the specific facts of each case.

Notes

<sup>1</sup> *Merck & Co. v. Teva Pharms. USA Inc.*, 288 F. Supp. 2d 601 (D. Del. 2004).

<sup>2</sup> *Merck & Co.*, 395 F.3d at 1376-1377.

<sup>3</sup> *Id.* at 1376.

<sup>4</sup> *Id.* (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)).

<sup>5</sup> *Id.* at 1377.

<sup>6</sup> *Galderma*, 737 F.3d at 740-41.

<sup>7</sup> *Merck*, 874 F.3d at 730-31.

<sup>8</sup> *Id.* at 1730.

<sup>9</sup> *Id.*

<sup>10</sup> *Acorda Therapeutics Inc. v. Roxane Labs. Inc.*, No. 14-882, 2017 WL 1199767 (D. Del. Mar. 31, 2017).

<sup>11</sup> *Id.*

<sup>12</sup> *Acorda Therapeutics Inc.*, 903 F.3d at 1339.

<sup>13</sup> *Graham*, 383 U.S. at 17-18.

<sup>14</sup> *Id.* at 36.

<sup>15</sup> *Kinetic Concepts Inc. v. Smith & Nephew Inc.*, 688 F.3d 1342, 1370 (Fed. Cir. 2012) (quoting *Mintz v. Dietz & Watson Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012)).

<sup>16</sup> *Catalina Lighting Inc. v. Lamps Plus Inc.*, 295 F.3d 1277, 1288 (Fed. Cir. 2002) (citations omitted).

<sup>17</sup> See *WBIP LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016); *Kinetic Concepts Inc.*, 688 F.3d at 1360.

<sup>18</sup> *Merck & Co.*, 395 F.3d at 1377.

<sup>19</sup> *Merck & Co. v. Teva Pharms. USA Inc.*, 405 F.3d 1338, 1339 (Fed. Cir. 2005) (Lourie, J., dissenting).

<sup>20</sup> *In re Cyclobenzaprine*, 676 F.3d 1063, 1082 (Fed. Cir. 2012).

<sup>21</sup> *Id.* at 1081-82.

<sup>22</sup> *Acorda Therapeutics Inc.*, 903 F.3d at 1339 (citing *Galderma Labs. LP*, 737 F.3d 731, 736-38).

<sup>23</sup> *Merck Sharp & Dohme Corp.*, 874 F.3d at 732-34 (Newman, J. dissenting).

<sup>24</sup> David Manspeizer, 'Blocking Patent' Doctrine May Now Apply to All Technologies, Law360 (Mar. 11, 2020, 10:02 AM), <https://bit.ly/2UNhEe2>.

<sup>25</sup> *Merck & Co.*, 405 F.3d at 1339 (Lourie, J., dissenting).

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