

Mending the Fence: Commercial Success and the Blocking Patent Defense in Pharmaceutical Litigation

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Obviousness

The U.S. Supreme Court's decision in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), established the key factors for assessing obviousness:

- the scope and content of prior art (existing knowledge in the field);
- the level of ordinary skill in the art;
- differences between the claimed invention and the prior art; and
- whether those differences would have been obvious to a person skilled in the art.

The fourth factor – whether differences between the claimed invention and prior art would have been obvious – often is evaluated considering six key “secondary considerations” or “objective indicia of nonobviousness:”

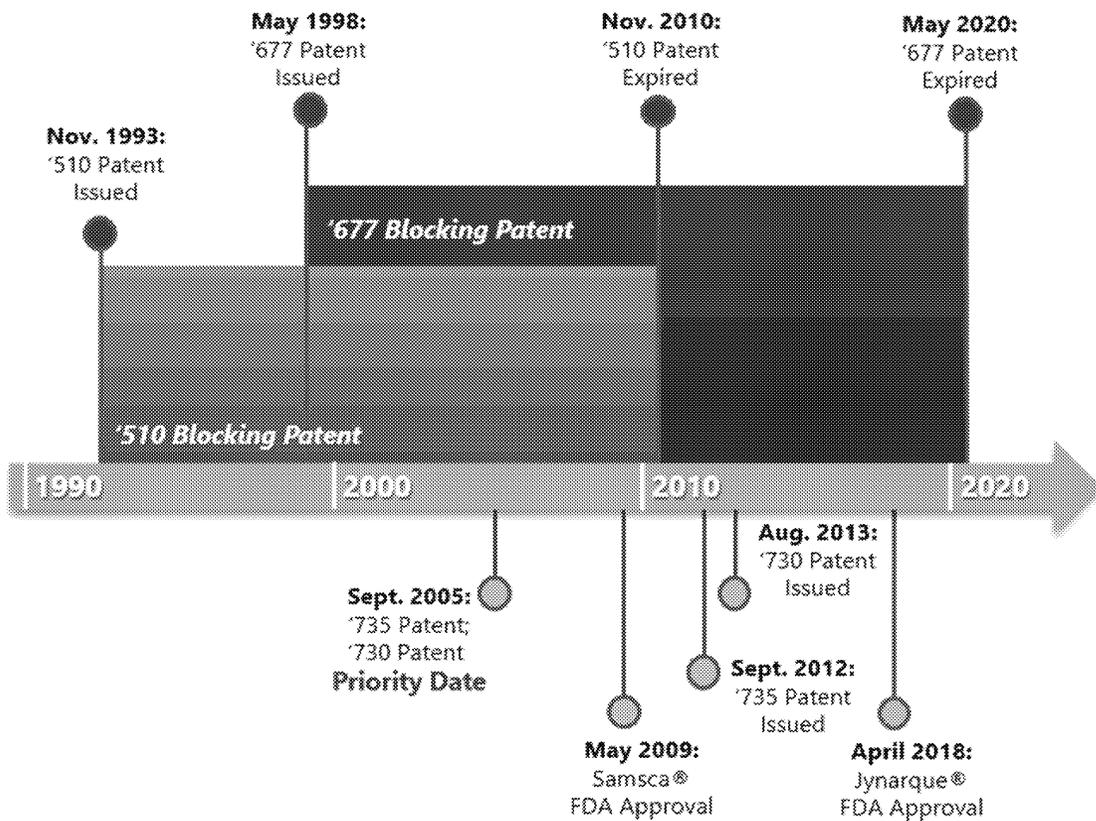
- commercial success,
- long-felt but unmet need,
- failure of others,
- copying by others,
- unexpected results, and
- licensing and industry recognition.



Commercial Success

- Marketplace Success
- Nexus

Blocking Patent Defense





Federal Circuit Cases

1) Case Name	At-Issue Patent					Blocking Patent			
	2) Patent Number	3) Priority Date	4) Grant Date	5) Expiration Date	6) At-Issue Compound	7) Patent Number	8) Grant Date	9) Expiration Date	10) Patent Type
Merck v. Teva (2005)	5,994,329	08/14/1998	11/30/1999	07/17/2018	Alendronate monosodium trihydrate	4,621,077	11/04/1986	08/06/2007	Method of Treatment
Galderma Labs v. Tolmar (2013)	7,579,377	09/10/2004	08/25/2009	02/25/2025	Adapalene	RE 34,440	11/09/1993	01/16/2012	Composition, Method of Treatment
	7,737,181	07/28/2006	06/15/2010	08/29/2024					
	7,834,060	05/07/2009	11/16/2010	05/16/2023					
	7,838,558	04/15/2008	11/23/2010	03/12/2023					
	7,868,044	05/03/2010	01/11/2011	03/12/2023					
Allergen, Inc. v. Teva Pharm. (2017)	8,629,111	08/14/2013	01/14/2014	08/27/2024	Cyclosporin	4,839,342	06/13/1989	08/02/2009	Method of Treatment
	8,648,048	08/14/2013	02/11/2014	08/27/2024					
	8,685,930	08/07/2013	04/01/2014	08/27/2024					
	9,248,191	03/21/2014	02/02/2016	08/27/2024					
Merck Sharp & Dohme Corp. v. Hospira (2017)	6,486,150	04/27/2001	11/26/2002	10/27/2020	Ertapenem	5,478,820	12/26/1995	11/21/2015	Compound
Hospira, Inc. v. Amneal Pharm. (2018)	8,242,158	01/04/2012	08/14/2012	01/04/2032	Dexmedetomidine	4,910,214	03/20/1990	07/15/2013	Compound
	8,338,470	07/03/2012	12/25/2012	01/04/2032					
	8,455,527	11/15/2012	06/04/2013	01/04/2032					
	8,648,106	04/22/2013	02/11/2014	01/04/2032					
Acorda Therapeutics, v. Roxane Labs. (2018)	8,007,826	12/13/2004	08/30/2011	05/26/2027	4-aminopyridine	5,540,938	07/30/1996	10/24/2019	Compound
	8,663,685	07/20/2011	03/04/2014	01/18/2025					
	8,354,437	04/08/2005	01/15/2013	12/22/2026					
	8,440,703	11/18/2011	05/14/2013	04/08/2025					
BTG Int'l Ltd. V. Amneal Pharm. (2019)	8,822,438	02/24/2011	09/02/2014	08/24/2027	Abiraterone	5,604,213	02/18/1997	07/25/2017	Methods of Use
Sanofi-Aventis Deutschland GMBH v. Mylan Pharm. (2017)	7,476,652	03/25/2005	01/13/2009	07/23/2023	Insulin glargine	5,656,722	08/12/1997	09/12/2014	System, Method of Manufacture
	7,713,930	12/04/2008	05/11/2010	06/13/2023		6,100,376	08/08/2000	09/03/2012	Compound
UCB, Inc. v. Actavis Labs. (2023)	10,130,589	01/31/2018	11/20/2018	12/22/2030	Rotigotine	6,884,434	04/26/2005	03/31/2021	System
						7,413,747	08/19/2008	09/21/2020	System

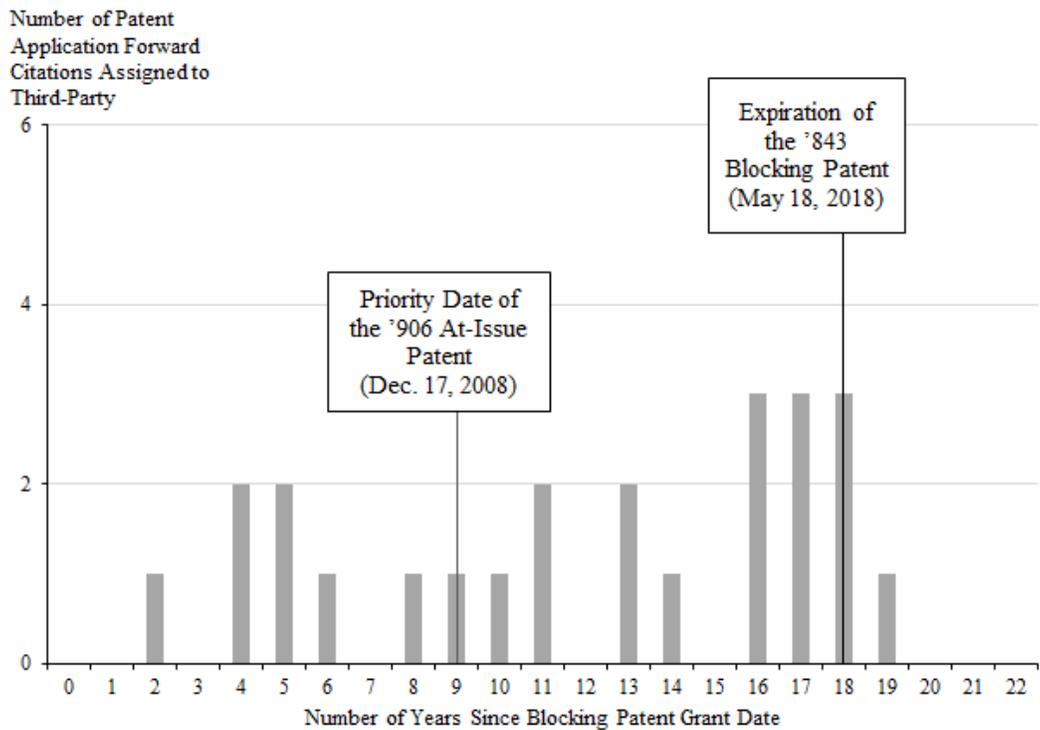
Blocking Patent Defense Problems

1. Not Often Relevant for Commercial Success
2. Not a Theoretical Construction
3. Not Dispositive as to Nonobviousness
4. Not a Block to Many Forms of Activity
5. A Fact-Based Issue
6. Not a Binary Choice

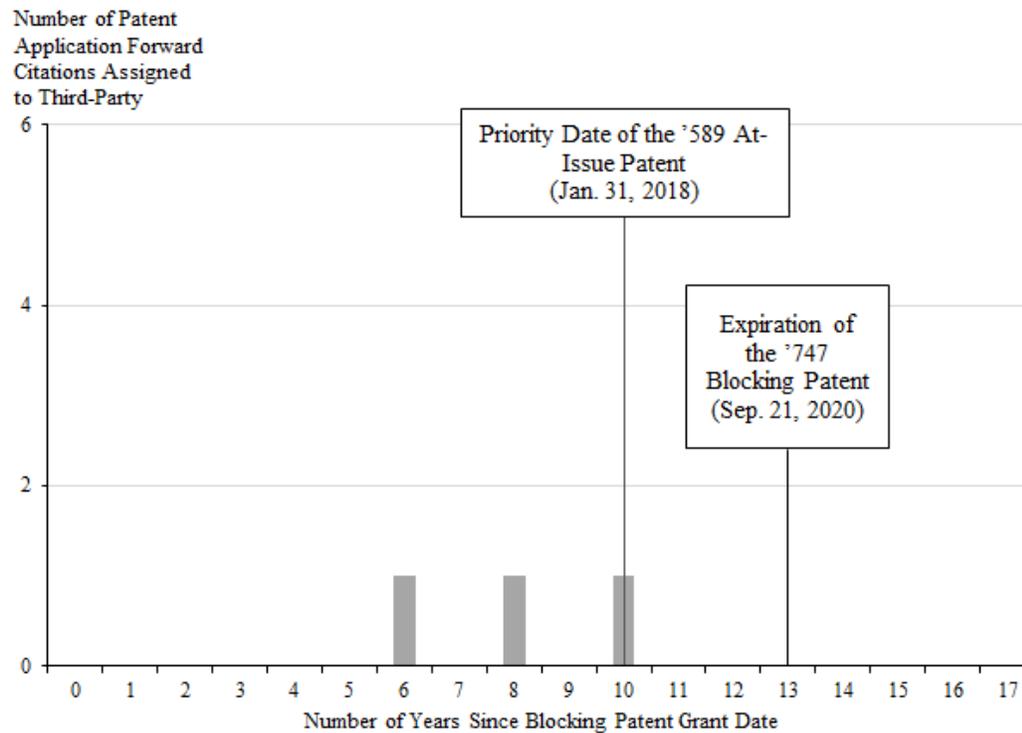


Forward Citations

Third-Party Forward Citations of the '843 Blocking Patent (*Janssen v. Teva*)

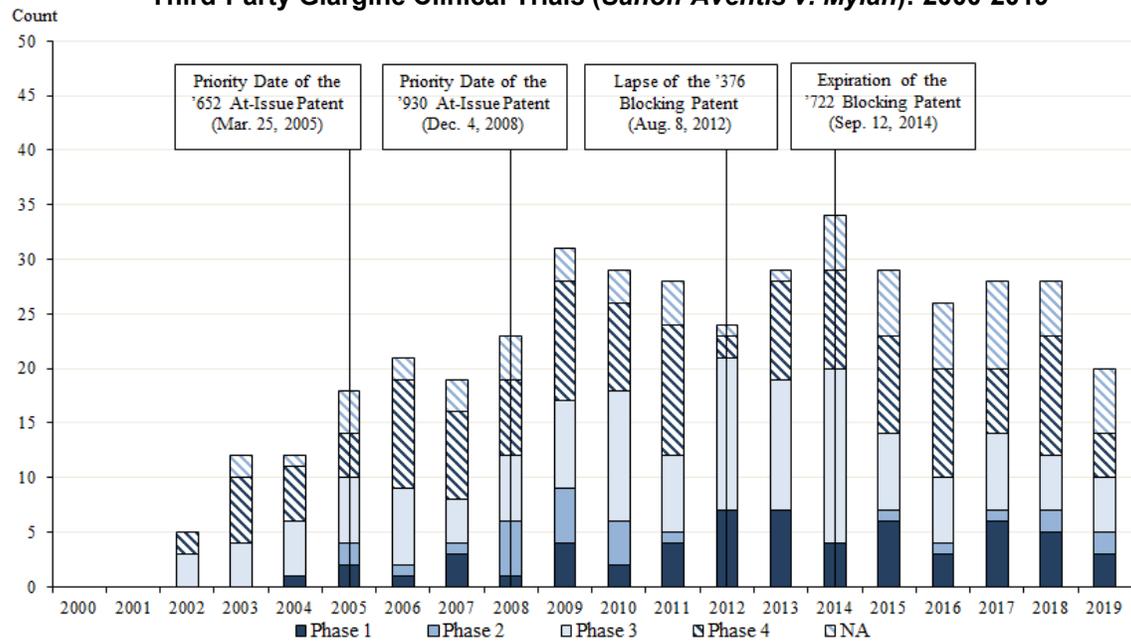


Third-Party Forward Citations of the '747 Blocking Patent (*UCB v. Actavis*)

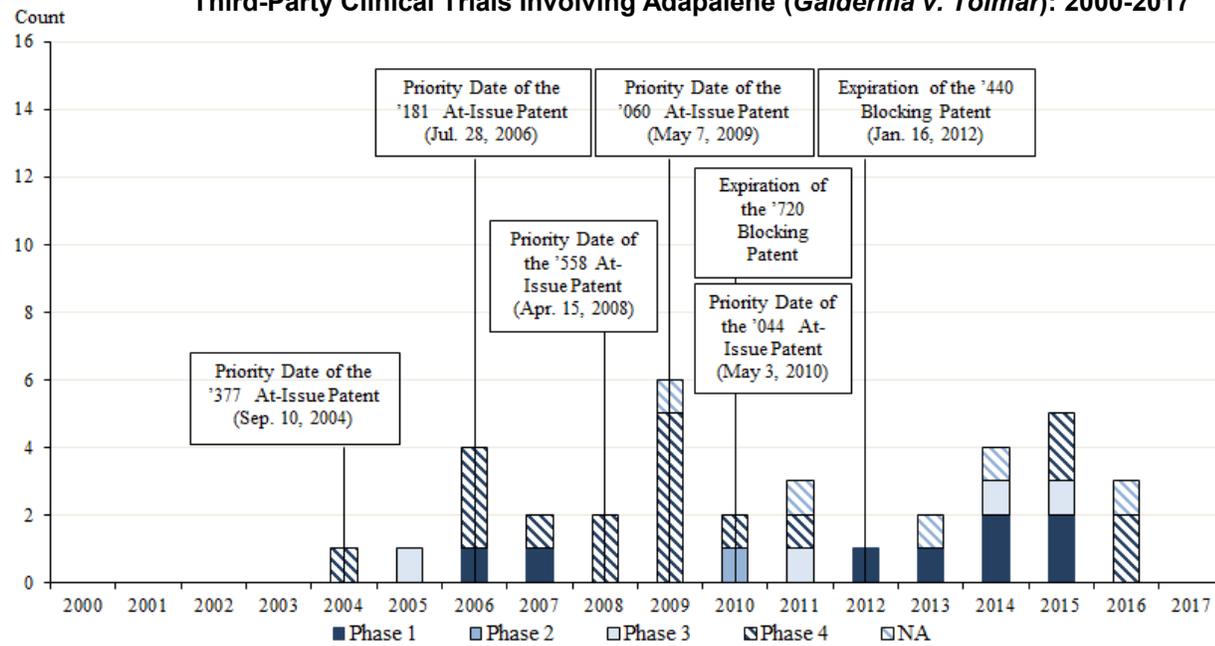


Clinical Trials

Third-Party Glargine Clinical Trials (*Sanofi-Aventis v. Mylan*): 2000-2019



Third-Party Clinical Trials Involving Adapalene (*Galderma v. Tolmar*): 2000-2017



Acorda Factors

- **challenging the blocking patent** – whether others believed the “blocking patent” could be successfully challenged;
- **costliness of the project** – the financial resources needed for successful research and development;
- **risk of research failure** – the likelihood that the project might fail scientifically or commercially;
- **nature of potential improvements** – whether the potential improvements are outside the coverage of the blocking patent;
- **market opportunities** – the size of the market anticipated for the potential improvements;
- **costs of development and commercialization** – the expenses required to develop the improvements and bring them to market;
- **risk of losing the invention race** – the possibility that the blocking patent owner or licensee might beat the potential innovator to the market with the at-issue improvements;
- **license availability and terms** – the risk that the blocking-patent owner might refuse to license the improvement or demand terms so burdensome that the project becomes economically unviable; and
- **other investment opportunities** – the weight of the above factors in relation to alternative opportunities for investment available to the innovator.

Blocking Patent Test

1. Evidence of Actual Inventive Activity
2. Evidence of Actual Blocking
3. Evidence of Potential Blocking
 - A. Nature of Opportunity
 - i. Opportunity Benefits
 - ii. Opportunity Costs
 - iii. Net Present Value
 - B. Nature of the Potential Block
 - i. Strength of the Blocking Patent
 - ii. Scope of the Blocking Patent
 - iii. Life of the Blocking Patent
 - iv. Patent Owner's Willingness to Share its IP

