

# Pepcid ac case study

[Business](#)



In recent years, the possibility of developing a lower dosage form of Epic for the ETC market became an attractive business proposition.

Merck was not alone in this venture, all major competitors in the H<sub>2</sub>O receptor antagonists market entered in a race to get FDA approval for a lower dosage version of its original prescription drugs, including Gallo and Sinkhole. In order to gain regulatory approval, drug makers must prove safety and efficacy of the medication. Furthermore, the willingness of consumers to comply with directions specified on the product label is also an important consideration.

Nine of the top-ten ETC brands introduced since 1975 were formerly prescription only drugs. A famous example of successful prescription to ETC switch was the pain killer David.

Not experienced in bringing prescription drugs into the ETC market, Merck joined forces with Johnson & Johnson, which had extensive experience in the consumer products market. The result was the creation of a mutually beneficial alliance known as KM. Being the first entrant into a new ETC market would present KM with a unique opportunity to potentially becoming the market leader in the H<sub>2</sub>O receptor antagonist

ETC market. The challenge for JAM, was obtaining FDA approval for Epic AC, the ETC version of Epic, ahead of its competitors. Testament was running head-to-head with Epic, trailed by Axle and Contact, which appeared not to have the same level of conviction to becoming first to market. In preparation for the filing with the FDA KM conducted clinical studies to support the claims of prevention and treatment of heartburn.

Conversely, Smithies adopted a different strategy, claiming only treatment efficacy.

Shortly after recommending against approval of Testament's ETC drug, the FDA divisor committee also recommended against Pepsin's approval and stated that JAM, " failed to show Epic, In Its low dosage form, either prevented or provided relief from heartburn. " 2- Problem Identification

According to data provide by AIMS America (Table A), In 1993 Epic ranked sixteenth among prescription drugs In the U. S. And third among H2O receptor antagonists.

The market leader Tort prescription H2O receptor antagonists was Lankan, Tallow Day Testament at a distant second place.

Considering Jims relatively low proportion of market share, and the fact that it has never been able to challenge Cantata's adhering, becoming the first in H2O class to enter the ETC market was critical for Jims ambitions of becoming the market leader in the highly lucrative heartburn treatment market. Another variable in this equation was the dual claim indication that JAM is planning to file. Being able to increase Epic Sac's customer perceived value by claiming prevention and treatment would allow JIM for product positioning within higher price range.

Considering that JIM already has a presence in the antacid ETC market with Implant, having Epic AC in a higher price range would be a way to clearly distance he 2 drugs from each other and reduce the risk of centralization. Additionally, Shininess's Testament is claiming treatment only, which would represent a competitive point of differentiation for Epic AC.

Furthermore, a higher price for Epic AC would also represent more revenue for JAM. The final factor to be considered in this study, is the FDA's record against prevention claims for ETC drugs.

Traditionally, the FDA prefers education over medication for purposes of prevention. The reason cited is the risk of verification that ETC drugs could pose if used for prevention of a disease. Three courses of action are possible for JAM at this point: (a) continue working with the FDA to make the case for the prevention and treatment claim with no delays; (b) drop the prevention claim and go with the treatment only claim, increasing the chances of approval; (c) conduct more clinical trials to support the prevention and treatment claims, but then delay the process and risk falling behind in the race to approval.

- Situation Analysis Strengths: Weaknesses: Epic AC safer than Testament (side effects when used with other drugs) Strong brand name. Convenient 1 tablet dosage Last longer than traditional antacids Indicated for both treatment and prevention of heartburning versus treatment only claim AT legate. Priced higher than traditional antacids Takes longer than traditional antacids to start acting Higher cost than Testament ( due to license fees) Opportunities: Threats: Move from 3rd place in Org H2O-blockers to 1st place in ETC Gain market share from traditional antacids competitors Growing market for H2O-blockers.

Testament, Contact and Said are also in the Org-ETC switch " race" Harder to reverse position after first year of market entrance Centralization of prescription version of Epic Centralization of Jam's antacid Implant.

Considering that Epic AC will enter the ETC market to compete against both H<sub>2</sub>O receptor antagonists and regular antacids the analysis of SOOT template above is broken down in 2 parts: Epic AC x Other He's: The two main competitors running to enter first in the ETC marketplace are Epic and Testament.

Comparing the Strengths and Weaknesses of both, Epic is safer to use with less restrictions when combined with other drugs, and is planning to claim both treatment and prevention of heartburn, versus only the treatment claim of Testament. On the other hand, Testament has a slightly lower total cost due to fees that JIM pays on Epic. Testament also has the advantage of having started earlier in the ETC transition process. The greatest opportunity for Epic against Testament, is the potential for gaining market share in the heartburn treatment market..

Another aspect to be highlighted, is the pricing strategy.

If priced too low, Epic AC could present a significant centralization risk to Epic. Epic AC x Traditional antacids: Similar to its competitors in the H<sub>2</sub>O receptor antagonists market, JIM has strong participation in the traditional antacid market. Jims Implant is second only to Shininess's Tums . The main strength of Epic AC versus Implant and other traditional antacids is the indication for both prevention and treatment (depending on the option chosen). Another import POD for Epic AC is its convenient one tablet a day dosage.

The opportunity for Epic AC is gaining market share from the other companies in the regular antacid market. Contrary to the opportunity, the <https://assignbuster.com/pepcid-ac-case-study/>

risk is that Epic AC may cannibalize Jam's Implant more than the other antacid brands. To avoid such possibility, JIM can develop a coordinated price and marketing strategies for Epic AC and Implant together. 4- Alternative Courses of Action The FDA advisory committee concluded that Jam's clinical trials did not show adequate efficacy of Epic AC in either preventing or treating heartburn.

As a consequence, there is considerable risk of rejection if JIM (a) proceeds with filing for regulatory approval for prevention and treatment claims with only the available clinical data. Although not a necessary rule, the FDA typically follows the advice rendered Day tenet valor's committee.

An alternative course AT Acton Is ( conduct additional clinical trials, in order to conclusively prove efficacy of Epic AC, for both treatment and prevention of heartburn. The caveat is that conducting additional trials could take an additional 6-9 months and Jeopardize Jam's goal of being first-to-market with an over-the counter H2O antagonist.

In the case of H2O antagonists, being first-to-market is perceived as an important competitive advantage, enabling the first entrant to capture and retain the bulk of market share. Furthermore, being first-to-market could facilitate establishment of long-term customer loyalty relationships.. The aforementioned strategy merits consideration because it increases the likelihood of regulatory approval, while also maintaining the ritual prevention claim (along with treatment), which JIM views as the key point of differentiation between Epic AC and Smelliness's Testament.

However, this approach could be viewed as overly conservative since JIM has already conducted extensive clinical trials to prove efficacy of Epic AC for both treatment and prevention claims. The most significant study was dubbed the “provocative meal study,” in which participants were given a dose of Epic AC or placebo, prior to consumption of meals certain to induce heartburn. JIM strongly believed that these trials already provided sufficient evidence in support of the prevention claim and that additional trials were unnecessary.

Therefore, conducting additional trials is a course of action to be pursued only as a contingency plan; that is, if regulatory approval is not achieved with the currently available clinical data. Alternatively, JIM could move forward with (c) filing for regulatory approval for the treatment claim only. This approach is believed to be the easier path to achieving approval, when compared to pushing for approval of both treatment and prevention claims.

Typically, the FDA views education as preferable over medication for prevention.

Therefore, the agency may have inherent resistance to approving prevention claims. As such, the potential for regulatory dismissal of prevention claims is a valid concern. Seeking approval for the treatment claim only may appear to be the easier path to regulatory approval, but this is not an option without downside risk. In pursuing this alternative course of action, JIM would be sacrificing their key point of difference and diminishing the value proposition of the product.

Furthermore, the lack of the prevention label could result in a significant reduction of market share and loss of revenue.

Although exults from BASIS market research support that treatment only claim is the most important one for product positioning, concept tests and focus groups support the notion that prevention and treatment together are more important. Additionally, heavy heartburn drug users, which account for the greatest potential usage and customer loyalty of Epic AC, strongly favor the treatment and prevention claims.

Therefore, pursuing treatment only approval may not necessarily be the best path forwards. 5-Recommendations and Implementations Despite the recommendations of the FDA advisory committee, JIM should still take the ease directly to the FDA and request approval of Epic AC for both the treatment and prevention claims. JAM has already conducted sufficient clinical studies supporting both indications.

The regulatory expertise from the Merck side of the JIM partnership should be able to make a compelling case in the regulatory submission seeking approval for both treatment and prevention.

Moreover, if the agency were to reject ten Telling JAM coo a teen opt Tort ten contingency plan leagues In ten Alternative Courses of Action section (Option (b)). Seeking approval for both treatment and prevention is clearly the best course of action. The prevention claim will surely be an important point of differentiation that will enable JIM to retain leadership in the ETC market once the other H2O brands receive their own FDA approvals.



JIM has performed extensive market research and has clearly segmented the market, targeted its customers and positioned their product well. Results from behavioral market research, reveal that most frequent antacid users are over the age of 50.

Furthermore, descriptive market research concluded that users of both antacids and prescription H2O receptor antagonists and heavy antacid users comprised 62% of Epic Sac's predicted dollar volume. Therefore, a marketing campaign primarily targeting these users is a natural course of action.

Furthermore, heavy users are likely to be early adopters of the new offering and tend to be opinion leaders, which will set the tone for the customer perceived value of the product Behavioral market research also revealed that patients that used prescription H2O receptors antagonists learned that with regular use of the medication they could prevent the onset of heartburn. This is a very important point for JIM, because they only have 13% of the prescription market (Table B).

Therefore, a marketing campaign emphasizing not only treatment, but also prevention, for a convenient ETC drug, could lure a significant portion of the remaining 87% of the prescription antacid market over to Epic AC. Research utilizing focus groups also concluded that prevention and treatment would be the most attractive form of product positioning.

Table B Market Share of Prescription Antacids Firm Prescription Antacid 1993  
U. S. Sales (\$ millions) Market Share Gallo Contact 1 , 694 56 Smithies  
Testament 528 17 Mere 387 13 Lilly Said 271 All Others 150 5 Analysis of the  
traditional antacid market is also critical.

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In this case, Jam's Implant has 16% market share off \$745 million market. Being first to market, with a superior product effective for a longer period of time than the competition and that also prevents heartburn, could be a significant catalyst for gaining market share from the traditional antacids. Results from BASES II tests established that 30% of prescription H2O receptor antagonists users and 28%-34% of antacid users would switch to Epic AC.

An aggressive advertising campaign could certainly improve these numbers.

In conclusion, considering Jam's relative small market share in both ETC and restriction markets for heartburn the potential gains with the switch of Epic, even after discounting possible centralization are significant. For example, 30% of the \$3, 030 million prescription market equates to \$909 million. Subtracting \$118 million, for the 13% of the Epic market share, yields \$791 million of potential revenue from centralization of the prescription drug market alone.

Of course, the price of Epic AC will be significantly lower, but even a 75% price reduction equates to nearly \$200 million in revenue. Similarly, assuming only 28% of the \$745 million ETC antacid market switches to Epic Ac would equate to nearly \$209 million in revenue.

Subtracting approximately \$33 million for Malaysia's market share and we are left with potential revenues of \$176 million. These examples also alleviate any concerns regarding sales centralization of prescription Epic and ETC Implant (Table E).

Though centralization will certainly occur, it will be tremendously offset by centralization of competing brands. To further support the notion that product positioning should be centered on treatment and prevention claims, JAM carefully determined their competitive frame of preference. As such, JIM assumed that Testament, the other leading product in the race for ETC H2O receptor antagonists, would position itself primarily based on its effectiveness in controlling stomach acid (I.

E. Treatment only claim) and also leverage its heritage as the original H2O receptor antagonist.

Treatment, the most important attribute of Testament, would therefore be the point of parity in product positioning of Epic AC, since both Jims Epic AC and Testament could be considered equivalently effective for the treatment of excess stomach acid. As previously discussed, the other eye attribute for Jims Epic AC positioning is the prevention claim. This would be the critical point of difference to cement Epic AC as the superior product, able to garner greater customer perceived value.

Prescription heritage of Testament is not deemed as important since it scored near the bottom of concept tests.

With respect to pricing, the \$2.95 price tag for Epic AC would render it competitive with antacids. However, a \$3.29 price would be appropriate due to its improved efficacy and prevention claim. Conjoint analysis evaluating the \$2.

95, \$3. 29 and \$3. 95 pricing snouts De performer prior to launch. –

Conclusion In addition to all considerations in the recommendations section of this report, it's important to emphasize that “ the race” to be first in H2O-receptor antagonists market doesn't end with the FDA approval.

The next phase, the product launch, is of equal importance. JAM will need to orchestrate a sequence of activities to make sure they are the first to hit the market with Epic AC.

Ramping up production and shipments to distribution centers and retailers is a massive effort. In Jims factories, all necessary resources and materials will need to be available for the first batches of Epic AC to be produced. Logistics will need to be in-line to move the drug from the factories through the supply chain and fill the drugstores shelves ahead of any possible competitor.

Additionally, a national advertising campaign will need to be standing by to go on-air immediately after FDA approval. Creating public awareness and having customers actually trying out the new product when it arrives will be key to obtaining leadership in this market.

For that, JIM will also need to train and incentive the pharmacists. Prior to the switch, Epic is still a prescription only drug, and as such, education and incentives goes towards doctors' offices and hospitals.

With the switch, pharmacists will be the first line of contact with the new customers; they will need to receive all necessary information to be able to explain to customers the advantages of ETC H2O-receptor antagonist compared to traditional antacids on the market. Following the initial

campaign, JIM will need to adjust the advertising strategy to focus on adoption and retention. According to the studies conducted by JAM, the fight for market share will be concentrated mainly in the first year after FDA approval.

Therefore, marketing campaigns during this period will need to be massive.