Namenda XR

ABSTRACT

This case focuses on the conflict between the Hatch-Waxman Act (enacted in 1984) designed to both (a) encourage pharmaceutical firms to make the substantial investment in new and improved drugs and (b) fostering lower prices through competition from generic versions with the reality experienced by pharmaceutical companies approaching the expiration of their patents.

Actavis, faced with experiencing the end of its patent on Namenda (a very profitable drug used in the treatment of Alzheimer’s and dementia) decided to introduce an extended release version (XR) with a patent extending through 2019. For a period of time, it marketed both the original and extended versions. However, despite offering incentives for patients to adopt the XR version, this approach, known as a “soft switch” was relatively unsuccessful. Actavis then announces that it is going to discontinue the original one-a-day version ... thus forcing patients to switch to the XR version and limiting the opportunities for generic manufacturers. This is known as a “hard” or “forced” switch. In doing so, the company ran afoul of the legal implications of the Hatch-Waxman Act.

**NAMENDA XR**

“Mr. Wilson is here, doctor.”

“Thanks, Connie. See you tomorrow.”

It had been a long day so Dr. James Henderson opened Jack Wilson’s file to refresh his memory of the case. Jack had been a patient of his for the past five years, and was being treated for a mild to moderate case of dementia of the Alzheimer's type.1 Dr. Henderson had prescribed Namenda; a drug only available by prescription, which was taken twice a day. He was relatively pleased by the results. However, he was faced with a problem.

He had recently received notification that Actavis [marketers of Namenda] was discontinuing Namenda (a twice a day prescription) and replacing it with Namenda XR (an extended version). This meant that Jack Wilson no longer be taking the medication twice a day but would be taking the extended version once a day. This also meant that Jack would be locked into purchasing Namenda XR and would not be able to take advantage of the lower prices that would normally be associated with a cheaper generic version of Namenda.

**The Development of Namenda (3,5-dimethyladamantan-1-amine)**

Namenda was first synthesized and patented by Eli Lilly and Company in 1968 and then developed by Merz Pharma in collaboration with Neurobiological Technologies, Inc., and Children’s Hospital, Boston/Harvard Medical School. It was then licensed to Forest Laboratories, Inc. for the U.S. and Lundbeck in selected European and international markets.

On October 17, 2003, Forest announced that Namenda, the first of a new class of drugs for Alzheimer’s disease, had been approved by the U.S. Food and Drug Administration (FDA) for the treatment of moderate to severe Alzheimer’s disease. The company expected the drug to be available to physicians, patients, and pharmacies in January 2004. Namenda was the first NMDA receptor antagonist to be approved for Alzheimer’s disease and the only therapy approved for the treatment of moderate to severe conditions.

 According to Howard Solomon, Chairman and CEO of Forest, “The introduction of Namenda fulfills Forest's commitment to the Alzheimer's community to bring a much anticipated therapy to the United States as quickly as possible. We believe Namenda, with its distinct mechanism of action, will open up the possibility for both monotherapy and combined treatment approaches in patients with moderate to severe Alzheimer's disease."2

**Introduction of an extended version**

 In 2010, the FDA gave approval to Forest Laboratories for Namenda XR, a one-a-day 28 mg form of Namenda. Forest launched this product while still offering the original 10 mg twice a day version. In 2013, Forest stopped offering discounts and rebates for the 10 mg version and began offering them only on the XR version. Lukas Simas in the Berkeley Law Journal used the term “soft switch” to describe this move (i.e., the introduction of a new version with minor differences from the original). It was not as successful as expected (i.e., patients continued to prefer the original 10 mg. version). So, in 2013, Forest announced that it was planning to discontinue the two a day version and replace it with the one-a-day 28 Namenda XR.

**The Implication of this Move (later described as “product hopping”)**

 In response to this announcement, GeriPal (a geriatric and palliative care blog) raised the question as to why Forest Laboratories was taking this step. It raised several possible medical reasons. However, it concluded that Forest was discontinuing the 10 mg. tablets because Namenda was going off patent in April 2015. This means that a host of low cost generic memantine would flood the market and replace non-generic Namenda in a year’s time.

 “So, how does a pharmaceutical company maintain market share when competing against low cost generics? Well the good folks at Forest have decided that if they can just move everyone who is currently taking Namenda to Namenda XR they won’t have to compete at all, since there in no generic version for Namenda XR

 So, what will patients experience? When they try to fill their prescription for Namenda 10 mg, they will find their twice a day pill is no longer made and will need to get ta new prescription for Namenda XR. Brilliant!”4

**The Importance of Namenda to Actavis (which purchased Forest)**

 Namenda had been a big seller. In the2014 fiscal year, the drug generated $1.5 billion in sales, while Narenda XR sales were $135.8 million, according to a filing with the U.S. Securities and Exchange Commission. So preventing erosion of these sales to cheaper generic copies is in the company’s interest. Namenda’s patent expires in 2015, while Namenda XR (the extended release version) has protection through 2029.4

 Meg,Tirrell, a columnist, observed that, “the company is counting on it being difficult for patients to switch medications once generic copies of the twice-a-day Namenda hit the market, after they've already switched to the once-a-day formulation. Quoting the New York attorney general, "A drug company manipulating vulnerable patients and forcing physicians to alter treatment plans unnecessarily simply to protect corporate profits is unethical and illegal. The company is counting on it being difficult for patients to switch medications again once generic copies of the twice-a-day Namenda hit the market, after they've already switched to the once-a-day formulation. A drug company manipulating vulnerable patients and forcing physicians to alter treatment plans unnecessarily simply to protect corporate profits is unethical and illegal." 5

 Other comments in this column included:

 “Actavis declined to comment on the suit but said in a statement that Namenda XR “has significant advantages over twice-a-day Namenda that are particularly meaningful for Alzheimer patients and their caregivers.”

Art Caplin, a bioethicist at New York University, commented that the fact that “the drug is for a particularly vulnerable population of mostly elderly patients with dementia makes the situation worse. One of the particularly morally pernicious aspects of trying to do a forced switch is you're doing it in a group of moderate to severely impaired people with Alzheimer's. The hard switch, I think, is fundamentally unethical."

 BMO Capital Markets analyst David Maris said that “if Actavis can't employ the forced-switch strategy, it leaves about $990 million in annual revenue "open to severe generic competition that was not open to competition before."

 While Actavis' stock rose following the filing of a law suit by the New York attorney (suggesting investors didn't initially anticipate the lawsuit would have teeth), Tirrell pointed out that analysts say they might want to pay closer attention—not just for Actavis' strategy, but for a technique employed across the industry.

 "This goes to the heart of the entire strategy," Gal said. "And to the extent that strategy becomes illegal, it will be a risk for the specialty pharma group, in particular, because they have been using this quite often. So this is something that the pharma industry will clearly object to, this is something we believe the payers will probably support, something we think the FTC will support. In other words, this will probably become a pretty big fight within the drug industry."

**The Drug Price Compensation and Patent Term Restoration Act (aka The Hatch-Waxman Act)**

 The Hatch-Waxman Act was enacted in 1984 and attempted to “advance the competing goals of preserving pharmaceutical companies ‘ incentives to make the staggering investments necessary to bring new, improved drugs to market, as well as fostering lower prices through competition from generic versions of branded drugs. Pharmaceutical companies depend on the higher prices they can often charge while their drugs are under the exclusivity protection of a patent – or other statutorily granted exclusivity, such as for orphan drugs – to recoup their investments in bringing the branded drug to market.

 On the one hand, the Act promotes price competition by allowing generic drug manufacturers to obtain expedited approval of the generic counterparts to previously approved branded drugs. The generic drug companies may enter the market using a streamlined application process – an Abbreviated New Drug Application (ANDA) – under which the generic drug manufactures may rely on data for clinical trials and other costly procedures already done by the branded drug companies, in order to make the showing necessary for

 Actavis was employing a strategy known as a “hard” or “forced switch”. According to Ronny Gal, a Sanford C. Bernstein analyst, it is “a technique employed with increased frequency in the drug industry as part of its product life-cycle management. This is when a drug maker launches a newer version of the medication and then removes the older product from the market before a generic version becomes available. This effectively pushes patients to switch to its newer medicine. This [would be] equivalent to Apple introducing the iPhone6 and then making all iPhone5s stop working.”6

**The Court Rules**

 On December 15, 2014, a federal court judge issued a preliminary injunction stating that:

1. During the Injunction Term as defined below, the Defendant (Actavis PLC) shall continue to make Namenda IR (immediate-release) tablets available on the same terms and conditions applicable since July 21, 2013 (the date Namenda XR entered the market).
2. On or before December 23, 2014, Defendants shall inform healthcare providers, pharmacists, patients, caregivers, and health plans of this injunction (and provide a copy of the injunction or other means to easily view this injunction) and the continued availability of Namenda IR in the same or substantially similar manner in which they informed them of the Defendant’s plan to discontinue Namenda IR in February 2014.
3. The Defendants shall not impose a “medical necessity” requirement or form for the filling of prescriptions on Namenda IR during the Injunction Term.

In order to allow for an orderly transition, this injunction shall be effective from the date of issuances until thirty days after July 11, 2015 (the date when generic memantine will first be available) (The “Injunction Term”).

 According to Ronny Gal in a research report, “the case has been closely watched because this is an attempt to apply the antitrust statute to a new field.” “If the decision holds, we expect the use of the practice would be heavily curtailed. Companies will have to switch much earlier and have to argue for lack of demand before discontinuing an older drug. It will also put payers in a broadly better negotiating position against drug companies.”

**Unclear Antitrust Implications**

 The Antitrust implications of product-hopping remain far from clear. The only decisions addressing product-hopping are from district courts in the context of a motion to dismiss. How these claims will fare at summary judgment or before a jury remains to be seen. Nevertheless, the existing product-hopping decisions provide some guidance:

* District courts have been likely to accept that, in some instances, allegations of product-hopping can support an antitrust claim for pleasing purposes.
* Courts have been unlikely to submit their judgment for the consumers about whether the new product is superior to the product it replaced.
* Instead, a product-hopping claim has been most likely to survive a motion to dismiss if it alleges some wrongful conduct in addition to simply changing the form of a branded drug.

 These broad principles could change quickly as new decisions emerge. Given the size of the annual market for pharmaceuticals, and the potential availability of treble damages in antitrust claims, product-hopping claims are likely to become more prevalent in the near future. Stay tuned.4

**Questions**

1. What makes this an ethical problem?
2. Should the development of drugs (with the potential to address various forms of dementia) be encouraged?
3. Do the theories of amorality and moral unity assist in evaluating the ethics of Activis and other companies?
4. What conclusions do you draw regarding the actions of Activis – specifically with regard to the issue of whether or not the company has acted in an ethical manner?
5. Which of the major stakeholders in this case will be hurt by Activis’ use of “product hopping”?
6. How should this situation be fixed? And which of the stakeholders should be responsible in this case?

**References**

**1. “**Types of dementia”. Dementia is a general term for loss of memory and other mental abilities severe enough to interfere with daily life. It is caused by physical changes in the brain. Alzheimer’s disease is the most common type of dementia accounting tor an estimated 60 to 80 percent of case.

2. http://www.eva.uategroup.com/Universal/View.aspx?type=Story&id=44710 FDA Approves Namenda (memantine HCL) For Treatment of Moderate to Severe Alzheimer's Disease Nationwide. October 17, 2003.

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5. Why You Should be Paying Attention to the Lawsuit Against Actavis” @megtirrell (http://twitter.com/megtirrell).

6. http://www.cnbc.com/2014/09/17/why-the-lawsuit-against-actavis-is-huge-for-biotech-pharma-investors.html

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**NAMENDA XR TEACHING NOTE**

ABSTRACT

This case focuses on the conflict between the Hatch-Waxman Act (enacted in 1984) designed to both (a) encourage pharmaceutical firms to make the substantial investment in new and improved drugs and (b) fostering lower prices through competition from generic versions with the reality experienced by pharmaceutical companies approaching the expiration of their patents.

Actavis, faced with experiencing the end of its patent on Namenda (a very profitable drug used in the treatment of Alzheimer’s and dementia) decided to introduce an extended release version (XR) with a patent extending through 2019. For a period of time, it marketed both the original and extended versions. However, despite offering incentives for patients to adopt the XR version, this approach, known as a “soft switch” was relatively unsuccessful. Actavis then announces that it is going to discontinue the original one-a-day version ... thus forcing patients to switch to the XR version and limiting the opportunities for generic manufacturers. This is known as a “hard” or “forced” switch. In doing so, the company ran afoul of the legal implications of the Hatch-Waxman Act.

**1. WHAT MAKES THIS AN ETHICAL PROBLEM?**

Ethics can be considered as being:

***An area of study that deals with ideas about what***

***is good and bad behavior***

Regrettably, there is no absolute measure of what is “good” or “bad” behavior. It is, like beauty, in the eye of the beholder.

All people have experienced situations where they believed they were acting in a good or appropriate manner only to discover that others held opposing views ... and regarded their actions as wrong and even reprehensible.

Whether an action is deemed good or bad depends very much on the views of the party (or stakeholder) making that decision. Thus, an issue becomes an ethical problem when two or more major stakeholders hold very different opinions as to whether a specific course of action is good or ethical.

In this case, there are a substantial number of stakeholders with very different points of view.

**2. SHOULD THE DEVELOPMENT OF DRUGS (WITH THE POTENTIAL TO ADDRESS VARIOUS FORMS OF DEMENTIA) BE ENCOURAGED?**

 Many students will see this as a relatively straightforward question and will conclude that, given the potential magnitude of the problem, the answer is obviously “yes”.

 However, others will argue that, while these conditions represent a serious problem, the development of drugs cannot be at the expense of any single element of society. The fact that Namenda XR has shown some degree of effectiveness (and generated 1.5 billion in sales) does not mean that Actavis should be given *carte blanche* relative to federal laws and regulations.

**3. DO THE THEORIES OF AMORALITY AND MORAL UNITY ASSIST IN EVALUATING THE ETHICS OF ACTAVIS AND OTHER COMPANIES?**

The theory of amorality suggests that business should be amoral (i.e., it should be conducted without reference to the full range of ethical standards, restraints, and ideals in society. Manager may use compromising ethics because competition distills their selfish attitudes into benefits for society (Daniel Drew 1797-1879).

By contrast, the theory of moral unity proposes that business’ actions should be judged by the general ethical standards of society, not by a special set of more permissive standards (James Cash Penney 1875-1971).

Most students will probably argue that, during the 20th and 21st centuries, society and legislation have moved away from the theory of amorality ... especially in the United States and other democracies. Business is now strictly judged by the general ethical standards of society.

 However, there may be considerable disagreement as to whether the theory of moral unity provides any real assistance in judging the ethics of Actavis with regard to Namenda and Namenda XR. Both sides could argue that they are acting within general ethical standards ... and it is the interpretation of those general ethical standards that led to the countervailing points of view.

Students may well identify a large number of ethical principles:

o The Categorical Imperative suggests that managers should act only according to that maximum by which you can at the same time will that it should become a universal law. Different stakeholder will have very different views as to what should become law.

o The Conventionalist Ethic ... Business is like a game with permissive ethics and any action that does not violate the law is permitted. The law is at the heart of the issue in this case.

o The Disclosure Rule .. Test an ethnical decision by asking how you would feel explaining it to a wider audience such as newspaper readers, television viewers, or your family. Clearly, members of the Actavis community would have no problem explaining their decisions and objectives.

o The Doctrine of the Mean ... Virtue is achieved through moderation. Avoid behavior that is excessive or deficient of a virtue. Defining that excessive or deficient of virtue will be extremely difficulty

o The Ends-Means Ethic ... The end justifies the means. Each of the stakeholders can use this rationale.

o The Golden Rule ... Do unto others what you would have them do to you. Again, this argument can be used by any of the stakeholder.

o The Intuition Ethic ... What is good or right is understood by an inner moral sense based on character development and felt as intuition. Intuition is extremely hard to nail down.

o Might-Equals-Right Ethic ... Justice is in the interest of the stronger. Government is designed to act as aa counterweight to might.

o The Organization Ethic ... Be loyal to the organization. All stakeholders are, hopefully, loyal to their organization.

o The Principle of Equal Freedom ... A person has the right to freedom of action unless such deprives another person of proper freedom. It is not clear that Namenda XR deprives anybody of their freedom ... except that it prevents patients taking the twice-a-day pill.

o The Proportionality Ethic ... A set of rules for making decisions having both good and bad consequences.

o The Rights Ethic ... Each person has protections and entitlement that others have a duty to respect.

o The Theory of Justice ... Each person should act fairly toward others to maintain the bonds of community.

o The Utilitarian Ethic ... The greatest good for the greatest number.

Students will differ as to which (if any) of these principles provide any real assistance in analyzing this case. The majority clearly do not while others lend themselves to interesting discussions if not resolution.

**5. WHAT CONCLUSION DO YOU DRAW REGARDING THE ACTIONS OF ACTAVIS – SPECIFICALLY WITH RESPECT TO THE ISSUE OF WHETHER OR NOT THE COMPANY HAS ACTED IN AN ETHICAL MANNER?**

 Ethics is not a clear-cut area. There are obviously many interpretations of the facts. This question should lead to an extensive discussion of the relationship between the nature of the shareholder and the specific circumstances.

 This, in turn, might well lead to a discussion of governmental policy, namely: what fundamental approach should the government take towards patents and product hopping. Should they forcefully apply existing patent law or modify it to expressly address the concept of extended version drugs.

**6. WHICH OF THE MAJOR STAKEHOLDERS IN THIS CASE WILL BE HURT BY ACTAVIS’ USE OF “PRODUCT HOPPING”?**

There are stakeholders with concerns over the usage of a drug such as Namenda XR ... stakeholders with very different perspectives and concern ranging from the afflicted patients to the halls of Congress.

***Patients***

Individuals suffering from dementia or Alzheimer’s disease are clearly the direct stakeholders. Their medical condition destroys their quality of life and places immense financial and psychological burden on their families and other care-givers.

Some poorer patients may not be able to afford the medication although most pharmaceutical houses, along with some nonprofits may help pay for the medication.

Negatively impacted may be some middle-income patients with limited health insurance coverage who may lose out on the opportunity to take advantage of the introduction of a generic version.

***The Prescribing Physician***

The physician prescribing a drug has two primary interests:

 o A concern with the well-being of the patient. In most cases, the medical practitioner has usually devoted their life to serving their patients and thus are concerned that they can provide them with the most efficacious medicine at a reasonable price.

 o A reliance on the pharmaceutical company to satisfy all legal and medical requirements and to provide them with supporting information to enable them to prescribe the drug with confidence.

Some physicians may see the replacement of the discontinued Namenda with the one-a-day version (Namenda XR) as limiting their ability to prescribe the optimal regime for their patient. However, the majority will probably see the extended version as simplifying the patient’s treatment.

***Pharmaceutical Companies***

If patients are at one end of the medical chain, the pharmaceutical companies are at the other. To stay in business, they need to be able to produce and market a continuous stream of new products. If they fail to do so then they will become the target for acquisition by other larger and more profitable firms.

“Product hopping” allows the company to extend the life of one of its more successful and profitable drug beyond the standard patent life.

***Corporate Employees***

If the pharmaceutical company does not remain profitable then the employees – ranging from the president to the researchers to the members of the staff – are all in danger being made redundant. Their loss of employment may well have a ripple effect through the immediate family and into the local community.

So, while employees may not be concerned with the prospects for a specific drug, they are likely to be in favor of the general concept of “product hopping” since it will add to the overall profitability of the organization.

***Corporate Stockholders***

Individuals who invest in the stock of a company do so in the anticipation that the company’s actions will result in (a) the sustained payment of dividends and (b) the steady appreciation in its value.

If “product hopping” supports the ongoing profitability of the company, the stockholders are likely to support the process. In most cases, the average stockholder’s knowledge of the ethics of the company and its actions is essentially limited to its annual report and other public pronouncements.

***Insurance Companies***

The insurance companies have an interest in the pricing and marketing of ethical drugs since their members/patients pass on a large percentage of the cost. The higher the differential between the cost of the brand name drug and the generic, the greater the pressure on the profitability and viability of the insurer.

“Product hopping” by a firm such as Actavis puts pressure on the insurance company since it prevents them from taking advantage of requiring lower cost generic versions of the drug.

***Other Pharmaceutical Companies***

Those firms wishing to introduce new formulations competitive with Namenda will be hurt by Actavis’ “product hopping” since they will be locked out of the market ... to the extent that doctors now prescribe the extended release version.

On the other hand, larger pharmaceutical companies will view Actavis’ action in terms of their own aging product line and, as these products approach the end of their patent life, will support Actavis’ “product hopping” as a mean of extending the life of their own product(s).

***The Federal Government***

The federal government’s regulatory bodies (the Federal Drug Administration, the Department of Justice, etc.) have three (3) distinct (and potentially contradictory) goals when it comes to the development and marketing of pharmaceuticals. They are to:

 o Encourage the development and promotion of new formulations. The idea behind the patent system is to encourage product development and provide the developer with a number of years of protection from competition thus allowing it to recoup the substantial costs associated with new product development and testing.

 Relative to this objective, the federal government may see the introduction of Namenda XR as a positive step ... if it can be shown that the extended version is more effective than the standard formulation. If it cannot then the “product hopping” will be merely an effort to avoid government regulation.

 o Prevent firms from having an indefinite monopoly on the sale of critical formulation thus preventing the entry of generic versions (at a considerably lower cost to the patient).

 In terms of this goal, Actavis’s action may well be seen as clearly contrary to the intention of the law.

 o Maintain the U.S. market from foreign competition (i.e., from countries where the price of pharmaceuticals is often considerably lower than in the U.S.).

 Actavis’ “product hopping” will be seen as aiding in the protection of the domestic market.

 ***Congress***

Congress enacted the Hatch-Waxman Act in 1984 to encourage pharmaceutical companies to invest the substantial amounts of money consistent with the development and testing of new products. However, it also had a second objective, namely: to encourage competition from among firms offering generic versions of the drugs (i.e., off-patent drugs).

As with any legislation, Congress is concerned with seeing its laws achieve the intended goals and objectives.

**7. HOW SHOULD THIS SITUATION BE FIXED? AND WHICH OF THE STAKEHOLDERS SHOULD BE RESPONSIBLE?**

As with any ethical situation, the two critical questions are:

o Which party has the motivation to change the current situation, and

o Which party has the power to implement a change in either the law or the application of the law.

Looking at the various stakeholders:

o Patients ... not an organized group and thus likely to have very limited power.

o Physicians ... unlikely to become organized unless they feel the XR version of the medication is dangerous to patients.

o Pharmaceutical companies ... within this community, firms will have very different view on this issue. While the pharmaceutical companies may come together as an association, many of the larger and stronger companies may well oppose action.

o Corporate employees ... will probably follow the company line set down by their top management.

o Insurance companies ... to the extent that they see “product hopping” as detrimental to their profitability, they may well lobby in favor of a change in the law ... making “product hopping” illegal.

o Other pharmaceutical companies ... their position on the issue of “product hopping” is likely to be heavily influenced by their size of the company and the nature of their portfolio (i.e., the extent to which their products are approaching the end of their patent life.

o The Federal Government ... the agencies of the government are responsible for interpreting and applying the laws passed by Congress.

 If the new Congress (as of early 2017) determines that the actions of Actavis represent an acceptable extension of the product life then it will not presumably apply the law with vigor. However, if “product hopping” is seen as unacceptable and undesirable then the government agencies will prosecute any leading companies trying to utilize this approach.

o Congress .... the new administration may conceivably call for action by Congress to clarify (i.e., revise) the Hatch-Waxman Act placing its emphasis where it believes the industry’s best interest lie.

While the agencies of the Federal Government can change the situation incrementally by bringing suits against those companies that engage in “product hopping”, Congress may decide to modify the underlying Hatch-Waxman Act and provide the federal agencies with a less contradictory set of instructions ... either to allow “product hopping” as a means of encouraging the larger pharmaceutical companies or preventing “product hopping” to encourage the smaller organizations and the development of generic products developed by smaller entities.

As of 2017, the Republican Party will have control of both houses of Congress (and probably the Supreme Court) and thus students will have an opportunity to look for major change in future legislation related to this issue.

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EPILOGUE

In June 2015, the Second Circuit upheld a preliminary injunction against Actavis finding that its “hard switch” strategy to launch an extended release version and delist the immediate-release version would likely violate Section 2 of the Sherman Act.

The Court held that because generic competition depends heavily on state drug substitution laws that allow pharmacist to substitute generics for branded products, the combination of launch and product removal constituted an anticompetitive “product hop” that would likely impede generic competition on the merits for the original immediate-release version of the drug. “Second Circuit Holds a Hard Switch Between Drugs is an Unlawful Product Hop under Section 2” [of the Sherman Act.

Given the growing costs associated with the development of new drugs [and thus the desirability of extending patent life], it is unlikely that the Second Court’s ruling will be long unchallenged.