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'Pay for delay' deals in the pharmaceutical industry

By Paul Belleflamme 1 October 2010 51

'Pay for delay' deals are commonplace in the pharmaceutical industry; they involve branded drug makers paying generic groups to delay the launch of lower-cost versions of their drugs. Last July, the US House of Representatives passed a legislation banning such deals. These deals are also at the center of European Commission scrutiny.

It does not take too much thinking to understand why big pharmaceutical firms propose such deals. What is more intriguing, at first glance, is that generic producers accept these deals. One can indeed wonder whether it wouldn't be more profitable for them to reap the profits of an earlier launch of their generic drugs rather than accepting the money that is offered to them if they delay. The explanation for this puzzle has been given in 1982 by Richard Gilbert and David Newbery in their article '*Preemptive Patenting and the Persistence of Monopoly*' (published in the *American Economic Review*). Douglas Clement (in his article 'Creative Disruption'), summarizes very nicely the main argument of this influential paper:

> "The Gilbert-Newbery model, then, says that a monopolist must choose between adopting an innovation and allowing a rival to adopt it. The monopoly firm must calculate not only the value of the innovation to its own operation, but the repercussions of allowing a rival to have it. In this situation, the economists showed, monopolists often have a strong incentive to innovate, if only to preempt their rivals."

Of course, what really matters for society, are the welfare effects of such deals. Are the US and European legislators right in trying to prohibit them? As usual with the economics of innovation, the answer is not simple; reasonable arguments can indeed be found for and against such ban (see for instance this recent Forbes article: 'Pay-For-Delay Or Pay-For-Innovation?'; see also the related post by Alain Strowel on this blog). On the one hand, delaying the entry of cheaper drugs certainly has a negative impact on the well-being of consumers in the short run. Yet, on the other hand, shortening the exclusivity period during which pharmaceutical firms enjoy monopoly profits is likely to reduce their incentives to produce new drugs, which may harm the consumers' well-being in the long run.

I would be happy to read your opinion about this complex issue.

About Paul Belleflamme

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51 Responses to *'Pay for delay' deals in the pharmaceutical industry*

Sophie d'Orjo 8 November 2012 at 11:54 #

Let us begin by a brief explanation of the problematic. A bill was signed in 2010 about the "pay for delay settlements". It prohibits agreement about it and therefore intends to try to reduce drug prices through a faster entry of generic drugs on the market. And I think that this decrease can be vital for many people.
Besides, according to the website Forbes.com, delaying generics to enter the market at the same time as monopolists, have consequences not only on pharmaceutical innovation but also on the future of the patients.
This rule prevents consumers to provide alternative medicines at a lower cost.

Jon Leibowitz (FTC (Federal Trade Commission) Chair) said about this subject: "It's time for the pharmaceutical companies to return to the side of Consumers."
In 1984 already, a law (the Hatch-Waxman Act) was passed in favour of the entry of generic drugs. However, these companies couldn't go against patents from innovative companies.

It also seemed important to point out that without patents, pharmaceutical companies couldn't produce drugs. Indeed, patents encourage scientists to conduct clinical trials and thus prove that the drug is effective. This is ensured by the fact that patents in the pharmaceutical sector are granted before the research is completed while in a other field, patents are granted once the research is completed. Otherwise, which consumers would be willing to buy a drug untested and unsafe?
So, that's why I think that the presence of a patent is significant.

However, the prohibition of pay for delay deals doesn't remove completely patents, but reduce its duration. Nevertheless, what could be the period of a patent?

On the one hand, there is a threat that laboratories are discouraged to produce new drugs because they are always at risk of being robbed their market shares by laboratories producing generics. Therefore there is a solution to that problem: if the pharmaceutical industry is afraid of being nibbled its profit, it could go up the slope by developing the market of "biologically-based" drugs.

On the other hand, pharmaceutical monopolists are unsatisfied: "Patent settlements are a vital appearance of a patent owner's intellectual property Ability to protect," said Matthew Bennett, PhRMA senior vice president of communications and public affairs. He added: "Retaining Ability to manage this litigation is Particularly critical for biopharmaceutical research-intensive companies, Which Rely on Their patents as a major incentive for the innovative work they do."

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- http://www.ama-assn.org/amednews/2012/07/30/gvsc0730.htm

Like: 0

REPLY

Adwait Karanjkar 8 November 2012 at 11:13 #

In my opinion, the first issue that is raised here is that why do generic drug makers decide to accept payment from firms having patents. I think this has to do with the unique nature of pharmaceutical industry. Even if you launch a generic product which is much cheaper than the patented drug, it does not ensure that the generic drug maker will be able to generate lot of profits out of it. In most Western countries, the drug sales are driven mainly by the prescriptions that the doctors write. With the huge marketing budgets that giants of pharmaceutical industry have, it is difficult for the generic players (which are usually much smaller) to compete with them in terms of marketing their products through doctors/hospitals. So, the generic drug makers find it easier to accept money from the patented drug maker than to compete with them in the open market.

As for the other issue, that innovation would be impacted if the exclusivity period is shortened, is a reasonable logic. However, when the patents are first granted, they last for a period of about 10 years, which is a significant period for the patented drug maker to generate its profit. Once the product goes generic, the patented drug maker loses a fair share of its revenues, however, it also saves significantly on the marketing expenses that it was incurring on promoting the drug over the period of patent.

Like: 0

REPLY

Lotty Njuguna 8 November 2012 at 10:00 #

I first attempt to dissect the nature of the industry in general and see if the pay-for-delay argument does make sense.
This is an R & D intensive industry and together with the biotechnology industry leads the rest of the sectors in investment in R&D. In 2010 for instance, according to the European Federation of Pharmaceutical Industries and Associations (EFPIA), the pharmaceutical industry had highest ratio of R&D investment to net sales (15.3%). The fact that this sector is R&D driven has historically made competition between players to be based on ability to bring in new products to the market rather than price of the product. The sot sunk into R&D is high compared to the variable cost that is incurred later to produce the drug.
This is an industry with a unique product life cycle ("PLC"). Unlike other industries, that follow the traditional arced PLC (i.e. market introduction, Growth ,Maturity and then Decline stage), the pharmaceutical industry has an extended R & D stage that has been stated to last 10-13 years, before the market introduction. Assuming the normal patent period of 20 years, this is an industry whose effective patent is 7-10 years.
Introducing generic companies to the equation, things become a bit complicated. For status, in a sector where intellectual property law was dominant, meaning that the kind of settlements that existed previously were patent holders being compensated by "infringers", pay-for-delay to generic pharmaceutical companies reverses this by having the patent holders compensate the generic pharmaceutical companies.
The pay-for-delay issue cannot be simplified by arguing just about fair trade or welfare. These thoughts work well in a perfect world and in as far as Europe and the US markets continue to dominate the industry in terms of market share of new products. However, the

reality on the ground is that this for status is an industry that accounts for 10% of the healthcare costs, is facing increasing competition as R&D activities now increasingly shift to emerging markets such as India, China, Brazil among others, it is also a high cost industry in term of innovation.
To circumvent this, the branded companies such as Sanofi-Aventis, have moved on to produced branded generics that have been diverted to emerging markets. At the end of it all, I believe any losses incurred by striking out the pay for delay settlement is countered by the introduction of branded generics.

Like: 0

REPLY

Diégo van der Wielen 8 November 2012 at 10:00 #

We have to keep in mind that the consumer must be the first focus of pharmaceutical companies, but without profit, there wouldn't be drugs at all.

So, on the one hand, I think that if the well-being of the consumer is harmed by the pay-for-delay of the big pharmaceutical companies, this practice should be prohibited. Because these companies work to help and heal sick people. But in some countries, medical assurances help people to access health care and drugs.

On the other hand, big pharmaceutical companies have to make huge profits in order to be able to invest in R&D. Research and approvals tests for news drugs cost an enormous amount of money. So if they pay generic companies not to launch a copy of the drug on the market and they still make unbounded profits, this companies could reduce at some point the price of their drugs, mainly if they are monopolist on this market (all the demand would come to them). In this case, authorities should intervene.

There should be a right equilibrium between the well-being of the consumers and the well-being of the firm…

Like: 0

REPLY

Valentine SIraut 8 November 2012 at 09:58 #

Nowadays the health system has to face two major challenges. On the one hand the incentive to innovate, asssuring to the innovative producers an exclusivity time on the market to make profitable its investments in research and development; on the other hand the health system has to deal with another challenge; promoting the developpement of generic medicine to reduce the cost of public health.

In the United-States, the first launcher of a generic product can benefit from exclusivity for 6 months with an price-average of 30 % less expesive that the original medicine. Then, when other companies entry the market the price of the generic product can be cutt down to only 20% of the original product.
In reaction to this very competitive market, multinationals have no other option but setting new strategies and focusing on "diversification" such as researching specific treatments. Moreover instead of the previous "blockbusters drug" strategy, defined as "an extremely popular drug that generates annual sales of at least 1 billion dollar for the company that creates it." with such a target, multinational were seeking more for profit in term of quantity, nowadays the laboratories center more it strategy on self-treatments, vaccines, veterinary sciences, new market, etc.

I found the growth of Sanofi, a good illustration. This multinational pharmaceutical company becomes the fourth-largest by prescription sales by the merger of Aventis and acquisition of Oenobiol, Chattem, BMP Sunstone. Throught those acquisitions the company tries to reach the emerging countries where 75 % of the globe population lives but where only 25 % of the consumtpion of drugs is consumed. This strategy leads to successful result to the French company that made in 2011, 9 milliards of euro that represents 30% of its profits outside the matures markets.(A.PARACCHINI,08/12/2011 http://www.lenouveleconomiste.fr/lesdossiers/laboratoirs-pharmaceutiques-la-falaise-des-brevets-13061/) .

In fact, I tend to think that the profit of pharmaceutical multinationals might be cuts down due to the largly entries of the generic products, the expiry of the patents, and the very competitive pharmaceutical market, there is an incentive for multinational to extend their activities to more opportunistic markets such as Asia where only the high level of the population can benefit from health treatement. This can positively impact on the well-being of consumers in long run around the globe.

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Like: 0

REPLY

Paul Belleflamme 8 November 2012 at 11:07 #

Nice closure to the very interesting discussion that you all contributed to. Thanks to everyone!

REPLY

Emil Bjornstad 8 November 2012 at 09:09 #

Many of the blog-comments have already highlighted how the difficulties of the pharmaceutical industry evolve around the fine line of reducing the high monopoly profits of the brand-name producers while increasing the consumers' welfare. At the risk of repeating everything that has already been said, this comment will not go into great detail about the vast complexity of the pharmaceutical industry or the ‹‹pay-for-delay›› deals. But the discussions on this blog made me ask myself the following question: With today's seemingly high levels of research and development 'needed' for new drugs, incurring astronomical costs for the brand-name producers, how could you make sure the incumbent firms have an incentive to innovate?

First, I feel the intensions behind the Hatch-Waxman act that was passed by the US Government in 1984 were good. The act was designed to promote generic drugs while also making sure there was an incentive for the producers to research and develop new products (1). As Simon Tremmel states in his comment, the act made it easier and more affordable for generic producers to challenge patents, and the consumers were better off having the option to purchase medicine at a lower price. However, the act made the incumbent brand-name drug producers the clear losers. Their profits were effectively reduced, as some of the monopolies were torn down.

So, abandoning ‹‹pay-for-delay›› deals or not, what the whole debate boils down to is how we can innovate, and invent new drugs, without ripping the consumers off by charging excessive prices. Unfortunately, the solution is, as always when dealing with economic inefficiencies, not as clear-cut as the question. However, there is one thing that the pharmaceutical industry must address in order to come any closer to a viable solution. And that is, to increase the productivity of research and development.

The pharmaceutical industry needs a sharp increase in the productivity of R&D in order for the incumbent brand-name producers to be sustainable from their increasing loss of revenues (2). Surely, costs of introducing new drugs on the market can be done more efficient than of those products that have dollar-figure-costs ranging from eight till ten digits. With an increased productivity through reduced costs, the producers may be able to launch the products at a lower price, while still sustaining their incentive to innovate.

So, before looking to abandon the ‹‹pay-for-delay›› deals, the industry should really look to revamping the inefficiencies that exists in the researching and developing of new products. This has to be done to make sure that the industry is sustainable in the long run with products at affordable prices, for the people that really need them.

PS! In fact, some people argue that some producers actually exaggerate the costs of R&D to justify higher prices for their products (3). Makes you wonder, doesn't it?

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2. http://www.nature.com/nrd/journal/v9/n3/full/nrd3078.html
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Like: 0

REPLY

Nathalie Dano 8 November 2012 at 08:34 #

I chose the pay for delay topic because it's a really important subject which is in the hearth of current pharmaceutical industry issues. It's a subject which is highly debating mainly because it doesn't only concern the consumers but also the government and for the most important part: money.
According to me, there are two schools of thought concerning this debate:

The first school of thought says that: Until the decision from the Supreme Court, the federal antitrust laws allowed a settlement, including retribution from the branded drug makers to the generic groups, but only as long as the settlement "does not exclude competition beyond the scope of the patent". According to some brand manufacturers (such as Merck, GSK or Pfizer), pay-to-delay are not 'lawful' and allow the generic manufacturer to be faster in the market (or at least sooner) than it might be otherwise. Furthermore, according to some generic groups, it was in fact a good way for them to enter the market sooner, and even easier for those generic drugs to be available months (or even years) before patents of big pharmaceutical industries have expired.

The second school of thought says that: those pay-for-delay deals can "harm the innovation and hinder the development of new drug products". According to one of the Federal Trade Commission (FTC) report, "between September 2009 and October 2010, more than 100 pay-to-play agreements were filed with the agency. Among them, 31 settlements, involving 22 different branded pharmaceutical drugs contained financial settlements to the generic competitor and restricted the generic company from selling its product." The US Senators Grasseley and Kohl agree with 'The Third Circuit Court of Appeals' saying that it's an important step to end up with those settlements which are abusive and unfair towards generic companies and which cost a lot to consumers and taxpayers.

I have to say that I it's really difficult to take sides for one of another solution. On one hand patents are really important to invest in new drugs (development,…) and on the other hand, patents are a big economic challenge for consumers, insurance companies,… which leads to a disagreement between the governmental institutions: the FTC treats pay-for-delay as anticompetitive and other institution

says that it doesn't "violate the antitrust law as long as the anticompetitive effects are within exclusionary power of the patent that covers the drug."
I guess we've to find a compromise but banning pay-for-delay agreements is really not the good solution because it will hurt the consumers and will reduce the incentive to innovate from big branded firms. We have to take into account the needs of consumers but also the needs of branded drug makers.

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Like: 0

REPLY

Navet Alexandre 8 November 2012 at 08:34 #

In my opinion "Pay for delay" is a concept which can be relevant in some types of industry.

In a theorist point of view, being a monopoly firm gives more profit to the company than being in a competitive market where the profit are divided between the several firms. But for the customer, a competitive market will decrease the price or will offer to him more choices of purchases. The monopoly threated by entry has to innovate to maintain his position and to sustain his higher profit (which will be less in case of duopoly). In a competitive market, the innovation can give to a firm a competitive advantage which wills increases maybe the rollover of the company.

Those conclusions are true but take in count only the economic point of view and not the other characteristics of a specific industry. The European commission fights the firms which are in monopoly position by given fines (for example: Microsoft) to "defend" the interests of the customers or to give the opportunity to an industry to develop herself.

http://www.journaldunet.com/solutions/0403/040325_microsoft_ue2.shtml)

"Pay for delay" is a concept that gives to the monopoly more time to enjoy his position. It is clearly against the way of thinking of the European commission and some investigations are made in the EU (http://www.nytimes.com/2012/07/26/business/global/pay-for-delay-drug-case-moves-forward.html?_r=0).

For me, the pharmaceutical industry is really special. The key success in this industry is the R&D but those researches take time and cost a lot of money. Enjoying the monopoly position will increase the length of the profit of a product. This profit can be invested to new researches. The customer wealth harms by the non-competitive market can nevertheless be higher if the profits given by the monopoly position are invested to researches which will maybe increase the efficiency of a drug. For me, when we are speaking about the healthiness of people, the economic point of view is not the only one which has to be taken in count. The utility of more profit (more researches for example) is one of the key points too.

Navet Alexandre

Like: 0

REPLY

Paul Belleflamme 8 November 2012 at 08:39 #

You write: "The European commission fights the firms which are in monopoly position." This is not correct. What the EC tries to prevent are *abuses* of dominant positions, not dominant positions *per se* (which often results from a sound competitive process).

REPLY

Franziska Grumbach 8 November 2012 at 07:09 #

In the following I will reflect my views on the economic and social effects of 'pay for delay' – its when a brand-name company with a valuable drug patent pays a generics company to drop a patent challenge. The goal is to delay the arrival of cheap generic alternatives .The earlier arrival of a generic would pinch profits that brand-name drug makers rely on. Both drug manufacturers benefit from these arrangements, but consumers lose out.

The agreements are the result of the Hatch-Waxman Act of 1984, which was supposed to encourage the entry of cheap generic drugs to rival the expensive patented versions.

The agreements generally work like this: A generic-drug maker comes up with a chemical equivalent to a large-selling, patented drug

and applies to the F.D.A. (Food and Drug Administration) to sell it, arguing that the patent is invalid.
Instead of wasting years and millions of dollars to defend the patent, the branded company often proposes a settlement: it pays the generic company to keep its drug off the market for a time period.
"In the case of Cipro, a powerful antibiotic with annual sales exceeding $1 billion, Bayer paid $400 million to a generic drug maker, Barr Laboratories, and other companies. In exchange, the generic makers said they would withhold their own lower-priced generic versions of the drug until Bayer's patent on the brand-name drug expired" (1)

"C. Scott Hemphill of Columbia Law School has calculated that on average a one-year delay in the entry of a generic version of a drug can cost consumers more than $660 million. He reached that conclusion by analyzing deals involving 51 drugs from 1984 to 2008. " (2)

It turns the market on its head, because generics earn more money by not competing than they would by entering the marketplace.
To conclude it can be said, that a greater access to generic drugs will reduce health care costs because the price of generic drugs is typically much lower than the brand-name drug. Reducing expensive lawsuits over drug patents and making the approval process more efficient will also help to lower national health care costs by reducing the cost of bringing safe and effective generic drugs to market.
On a personal level, it is once again shocking how little the individual counts in society, but it is all about profit and power.
Even if in some countries health insurances cover many medical costs this health care system is missing in many other countries. So it hits again the poor who'll find themselves in dept for obtaining drugs because the pharmaceutical industry holds back generic products many years so they can continue to maintain its monopoly and thus determine the usually high prices without competition.
It's time for the pharmaceutical companies to return to the side of consumers.

Example

http://www.businessweek.com/news/2012-02-09/pfizer-ranbaxy-sued-over-alleged-anti-competitive-scheme.html

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Like: 0

REPLY

Paul Belleflamme 8 November 2012 at 08:27 #

You write: "It turns the market on its head, because generics earn more money by not competing than they would by entering the marketplace." This is exactly the result that we can establish by referring to the "efficiency effect" of Gilbert and Newbery.

REPLY

Malaika Rousseau 8 November 2012 at 06:53 #

The "Pay for delay" practice in the pharmaceutical industry is a very complex issue.

In one hand, the branded pharmaceutical manufacturers face very high fixed costs for the production of new drugs and estimates of average R&D costs for successful drugs can reach hundreds of millions of dollars. Intitila drugs entering the market will therefore be high, to allow the branded manufacturer to recover its fixed costs and be adequately compensated for its risk-adjusted investement.
And the entry of generic firms will therefore push the market price down and the branded firms will get a lower profit.
Furthermore, the public authorities allow patents to branded firms which do not necessarily provide market power but they do confer this exclusivity that they need to secure their investment and to stimulate innovation.

On the other hand, the generic pharmaceutical firms' entry provide consumers with substantial savings. In the US, the first generic competitor typically enters the market at a price that is 20 to 30 percent lower than its brand name counterpart, and savings may be reach up to 80 percent in the long run. In one 2006 study examining the pharmaceutical markets of 11 European countries calculated savings from generic substitution for the top ten branded substances by public expenditure in each country, based on data from 2004. The study found that increased generic substitution would bring additional savings of at least 21 percent in each country examined, with higher savings rates estimated at 48 percent for Denmark, 47 percent for Germany, 35 percent for France, 33 percent for the UK and Spain, and 31percent for Italy.

However consumers benefit not just when existing drugs sell at lower prices, but also when new and more effective drugs reach the market over time. The positive welfare effects from such long term benefits can be much greater than the staic benefits from short term price decreases.
This does not mean, that authorities should give endless monopolies for branded pharmaceuticals firms but that they have to balance static and dynamic welfare effects.
Once the branded firm has recouped its investment, generic producers should then be allowed to enter the market and delaying those

entries by "pay-for-delay" practices can be harmull at long for the welfare society.

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Like: 0

REPLY

Paul Belleflamme 8 November 2012 at 08:22 #

Good. Thanks for the references.

REPLY

Christian Ramirez Ledezma 8 November 2012 at 00:19 #

Pharmaceutical industry unlike many other businesses is unusual in that, unlike a company that builds cars or any other product, the experimental phase is much more complex as they have to ensure that the product actually has to work for what was created and with the particularity that it is not as easy as taking a group of people, give them a drug and see if it works or not. It is an experimental process much longer in which gradually with small control groups and with people who need the product keeps records if the results are as expected. Even this stage can last for many years as they have to consider the long-term consumption of a drug. Is not as easy as building a car and make destructive testing to see if the safety systems work well, you can do this whenever you want, but you cannot supply a drug to a person to see what the reaction is on him, because we are talking about a life.

Even with all that time and resources pharmaceuticals devote to product development, it is common to see (and much depends on each country) that some drugs are removed from the market because its consumption can cause side effects that were not taken into account until it was released and a lot of people took it. And it is not easy to realize it because you have to gather information from different hospitals, in different countries and continents.

Because of that hard work that these businesses dedicate to developing new products, I think there should exist any extension period so they could make more profit from something they created, otherwise they are forced to make those practices that at glance doesn't seem legal. On the other hand, people, especially those with limited resources, will have to wait longer to enjoy a product with the same formula but cheaper.

I won't go into the discussion about the quality of generic products against known brands, but for me it is clear that a greater social benefit could be obtained from offering cheaper products to people who probably would not buy them because of high prices, against the benefit the companies could obtain of the extra period of exclusivity of a product, even when it can be argued that this revenue would be allocated to the development of new products, because calling to my comment in the previous article, I think the more competition exists, in some degree, more innovation it will be.

Like: 0

REPLY

Xuning Zhang 8 November 2012 at 00:09 #

In pharmaceutical industry, business cycle are very long, from start up of innovation to medicine sales could take years. Also, resources like technology, money supply and human resource are quite scarcity so that for now only big drug makers have the ability to innovate new medicine while generic groups could only create lower-cost version instead of inventing new drug. Without Pay for delay policy, imitate drug would come out within 6 month and take over the market. So for now, pay for delay is a practical way to help drug makers get more cash back and win the time for patent expired, thus keep business running and develop new inventions.

Pay for delay have no harm for generic group either, on the contrary it could bring extra profit and booming the industry, though only the imitating industry for now, but with competition, imitating would head to innovation in the end.

The only inconvenience would be for consumers since drugs are with low elasticity, they would have to buy no matter its expensive or not. In countries with relatively complete welfare system, for instance in the U.S, big share of costs are covered. For instance, in the Cipro case, the U.S government would have to pay 4.8billon dollar for the 'pay for delay' as the Medicare is the main consumer in the country. Thus, it could be seen as government is paying more for delay instead of the consumers, in another word pay for innovation.

Pay for delay is a quite good strategy in the short run; the huge cost would stimulate government macro policy and tax preferential for pharmacy industry. But in the long run, with force of globalization and technology, pay for delay could be too costly to work, despite the macro policy, pharmacy companies have to change its invention system in order to develop in the future. As long invention time is one of the key issues, a possible solution for drug maker could be segmentation the innovation, separate the medicine with real innovative therapeutic value from other common medicine with less therapeutic value, use different strategy for different type of medicine.

Reference:

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http://californiawatch.org/dailyreport/state-court-examine-pay-delay-deals-drugmakers-15133

Like: 0

REPLY

Gaurav Sushil 7 November 2012 at 23:32 #

The settlement between the branded drug makers and the generics to delay the low cost version violates fair trade and is restricting the access to low cost drugs. In this way the branded companies buys out time and maintains monopoly for a longer period leading to more profits more the branded drug companies.
But victim here are the consumers, these settlements allow the drugs to be sold at higher prices that is eventually paid by the consumers. Most of the times generic drugs are sold at 90% less than compared to its brand name equivalent. Without pay for delay option these drugs can be sold in generic market, which would lead to competition and drugs will be available at marginal cost.
If the branded drug companies are not making profit of the drugs and hurting themselves then the issue is to have a look at the duration of the patent but not to give them a option to pay for delay.

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Like: 0

REPLY

Pedro Carrascoso Jiménez 7 November 2012 at 20:35 #

Sometimes we tend to represent the generic pharmaceutical industry, as a Robin Hood who steals from the rich (industry brand drugs) and give to the poor (health services and patients) in the Sherwood Forest of medicine. This is not entirely true, as we see in many readings.

The reality is very different, here there is no attempt to help the patient or health care, in this world and in almost all the most important thing remains the economic power of each. It is sad to think that in this market the most important non-life and health of people, but money and power.

In some cases the generic industry, in return for a substantial compensation paid by the company owning the brand name drug, delay marketing of generic.

In this case the company owning the brand name drug would benefit from a larger preview of fact in the data exclusivity period. Then it is clear who ultimately pays: patients and health services, which continue disbursing an unnecessary amount, if competition mechanisms operate properly.

The lack of transparency and the usual margin for agreements that harm to final consumers are the ideal setting. Meanwhile, it seems that patients and consumers associations deviate too much of a common view that "brand is quality."

Perhaps part of the blame has to defend society itself branded products, perhaps the society is not aware of the serious problem of "pay for delay", but perhaps governments and corporations do not want to make society aware of this problem and keep filling their coffers with money from all of us.

I leave you two references that in my opinion are very interesting. One of them was from the FEDERAL TRADE COMMISSION, specifically from his Chairman, Leibowitz in 2009.

http://www.ftc.gov/opa/2009/06/capspeech.shtm

The second one was from The New England Journal of Medicine, in 2011. "Pay for Delay" Settlements of Disputes over Pharmaceutical Patents.

http://www.nejm.org/doi/full/10.1056/NEJMhle1102235

Like: 0

REPLY

Paul Belleflamme 7 November 2012 at 21:12 #

Thanks for the thoughts and the references.

REPLY

Myriem Majid 7 November 2012 at 18:57 #

The company's agreement between the generic company and the brand drug firm violates the fair trade by keeping the drug off the market competition.

In one hand, this delay ensures that the name-brand drug can stay longer under monopoly which allows to charge high prices and therefore to have more profits.
However, the cost of the delay is the sharing of the brand's monopoly profits. So, the name-brand drug looses profits.

On the other hand, the victim of the agreement is the consumer because he could have the same drug at a lower price. Indeed, it restricts the consumer's access to low cost drug allowed by the generic drug. Consequently there is a deadweight loss because the drug is not produced at an efficient cost. By contrast, if the product enters in the generic market, there will be competition. And as a result an efficient allocation will be reached because of the pricing at the marginal cost.

Moreover, the longer the name-brand drug is under monopoly, the more the incentive to innovate is high because a longer patent duration will protect longer the innovator from competition.

From my perspective as a consumer, the second argument is more relevant. The government regulator has to protect the consumer from this anticompetitive union. To reduce the incentive to pay the generic competitor, the regulator could for example fix a price cap to deter the name-brand drug to delay the entry of generic products.

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http://www.ama-assn.org/amednews/2012/07/30/gvsc0730.htm

Like: 0

REPLY

Julien Caufriez 7 November 2012 at 18:49 #

The pay-for-delay legislations being debated in the European and U.S. political spheres tackle a complex issue. Should monopolies be able to pay firms willing to enter into the market in order to delay that decision?
From the consumer's perspective, it is easily understandable why people would want these types of legislations to pass; they have to wait longer in order to have access to the more affordable option. There is definitely a negative impact on social welfare on the consumer's surplus side.
However, drug companies argue that these kinds of deals are necessary in order to innovate. As we know, R&D costs represents a huge chunk of the drug company's costs; hence, benefiting from monopoly profits for a longer period allows the company to accumulate more profits to be then later used in more R&D for other drugs. According to this argument, allowing pay-for-delay deals would have a positive impact on social welfare by allowing drugs onto the market that wouldn't have been invented otherwise.
From a purely economic perspective, the pay-for-delay deals make sense:
- Let's assume the monopolist produces the drugs for 1 period then it becomes available to entry.
- Let's call the monopolist's profits (in any period) $\pi(m)$.
The generic drug company, if it enters, will make profits $\pi(g)$ S <$\pi(m)$- $\pi(g)$, this is optimal :
- The monopoly earns $\pi(m)$ – S, which is higher than the profits it would have made if it let the generic firm enter ($\pi(g)$)
- The generic firms earns S, which is higher than the profits it would have made by entering the market ($\pi(g)$)
Based on this simple theoretical model, these legislations seem unnecessary.
However, the issue is very complex. As mentioned in a 2004 "The Economist" article, monopoly situations can have a negative impact on innovation, since the firm is only competing with itself. There is no proof that during the prolonged monopoly situation allowed by the pay-for-delay deal, the monopoly is actually working on innovation (and not just accumulating profits for a bit longer).
It is definitely to conclude whether these deals should be made illegal since it relates to very long term changes in social surplus, which is very hard to measure.

Like: 0

REPLY

Nicaise François 7 November 2012 at 15:32 #

The most important issue is the reason why a drug is put on the market: to treat people. Indeed, pharmaceutical market isn't a market like the others. You can't play with people's life. This must be the only factor of decision in my opinion. On one hand, for this kind of product, delaying the launch of cheap drugs can be seen as the opposite of what a drug is made for. Delaying don't help people in need at all, the drug has to be the cheapest and put as soon as it is possible on the market. On the other hand, to be able to create new drugs to treat new diseases and help patients, we must encourage compagnies to invest in innovation. But the point is that you can't tell to firms to invest, and not reward them enough long for what they've invest. Patents are made to protect and warrant them a monopoly during a specific period of time.

However, in an economic point of view, paying some firms to have the monopoly for a while is illegal. In every other market, a society,

which wants to pay to be the only one in the market, would be roughly punished.

The problem linked to the "pay for delay" deals is hard to solve but if we accept these kinds of pratics, we must at least control them very seriously. We have a right of look because the whole society pays for the pharmaceutical products. Indeed, social security or insurance take in account most of the time in account a part of the cost of these products. Maybe we can supervise this very specific sector with a "regulation". The price, for example, could be controlled by taking mainly in account the social aspect. The monopolist could then benefit from his monopoly position, and in the same time with a maximum level of the price, the society is able to treat people in an as efficient as possible way. The goal is to find a trade off between societal costs, level of innovation and drugs access.

http://www.forbes.com/2010/07/15/drug-patents-pharmaceuticals-opinions-contributors-anup-malani.html

http://www.nejm.org/doi/full/10.1056/NEJMhle1102235

http://www.wipo.int/wipo_magazine/fr/2010/01/article_0004.html

Like: 0

REPLY

Paul Belleflamme 7 November 2012 at 15:51 #

I agree with you on the specific nature of pharmaceutical innovations. As I wrote in a book chapter: "When it comes to pharmaceuticals, static efficiency could even call for prices *below* marginal cost, because these products generate positive consumption externalities in terms of improved public health. To put it bluntly, the abstract 'deadweight loss of monopoly' takes a much more concrete and tragic form here, which can be measured, following the World Health Organisation, in *disability-adjusted life years* (DALYs) lost." (see How efficient is the patent system? A general appraisal and an application to the pharmaceutical sector. In A. Gosseries, A. Marciano and A. Strowel (eds.) *Intellectual Property and Theories of Justice* (2008). Palgrave macmillan. http://www.palgrave.com/products/title.aspx?PID=276257)

REPLY

Simon Tremmel 7 November 2012 at 13:44 #

I would like to state my opinion to this complex, but very interesting issue. The US Federal Trade Commission (FTC) describes the Hatch-Waxman Act as a framework which was designed to "balance an expedited FDA approval process to speed generic entry with patent term restoration to ensure continuing innovation", while a federate appellate judge mentions the act's purposes: inducing "brand-name pharmaceutical firms to make the investments necessary to research and develop new drug products" and "simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."(1) At first glance, the act seems to be a win-win solution for all concerned parties. In fact, the incumbent brand-name manufacturer has a strong incentive to keep generic manufacturers as long as possible out of the market and is therefore interested in a workaround, which leads to a drawback for society.

The Hatch-Waxman Act effectively grants a 180-days monopoly in the generic market to the first generic manufacturer, provided no valid patents are infringed. In order to avoid that waiting time, generic drug manufacturers started to dispute the validity of patents. Referring to a 2002 FTC study, "generic applicants have prevailed in 73 percent of the cases in which a court has resolved the patent dispute."(1) Regarding that figure, it is reasonable for generic drug manufacturers to go to court, because they can more than likely sell their products sooner on the market and furthermore society (in form of patients) also benefits from the resultant faster access to cheaper generic drugs. But the incumbent's incentive to maintain the monopoly prevents this benefit in most cases. Considering R&D costs of their patented products and possible earnings from a longer monopoly, those pay-for-delay deals appear to be very profitable for the brand-name companies, and therefore they try to achieve out-of-court settlements with generic companies.

I find it interesting that generic manufacturers accept those deals, so the payout by the incumbent has to be significant in comparison to the lost earnings due to the delayed market entry.
The reason for this must be situated in the difference in monetary value of brand-name and generic drugs. According to IMS Health, generic drugs become more and more important, since "80 percent of prescriptions were dispensed as a generic in 2011" in the US, but generics only amount to 27 percent of total drug spending.(2) This stresses the importance of pay-for-delay settlements for brand-name companies, because another couple of months selling high-priced drugs enables the companies to obtain a larger amount of the total spending, which is why paying generic manufacturers or withholding an own "authorized generic" becomes economically reasonable for them.

It is clear that brand-name companies rely on monopoly profits of their patented drugs, otherwise incentives to innovate would shrink. Nevertheless it is also important to find a policy that generates an advantage for society. The decision of the 3rd US Circuit to declare the settlements of Schering-Plough illegal(3) does not surprise, because from the point of view of society there are no visible advantages. I am not sure if there can be long-term solution to this issue, because there is a lot of money at stake for the pharmaceutical companies, so they may always find a workaround. But it is necessary for judiciary and policy to pick up that issue in the interests of society.

Sources:

(1) http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf
(2)

http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf
(3) http://newsandinsight.thomsonreuters.com/uploadedFiles/Reuters_Content/2012/07_-_July/3rd_Circuit%20K-Dur_Decision.pdf

Like: 0

REPLY

Paul Belleflamme 7 November 2012 at 15:57 #

Excellent!

REPLY

Yousra Ebrahmi 7 November 2012 at 12:09 #

In January 2010, the Federal Trade Commission released a study called Pay-for-Delay: How drug company pay-offs cost consumer billions. I think that this report gives a clear background of the issue.

1. BACKROUND

The drug market is an artificial monopoly, largely based on exclusivity, in terms of time, through patenting. Once the patent expires, we are in the presence of an oligopoly with substitute products in terms of features and lower prices. There are two different types of «players" in this industry:
• The generic pharmaceutical companies seek entry prior to expiration of the patents on a brand-name drug.
• And the brand-name pharmaceutical companies that try to maintain their exclusivity at least for the time stipulated in the patent.

Let's first focus on the generic companies: To gain access to the market before the end of the patent, the generic companies must seek Food and Drug Administration (FDA) approval by declaring that its product does not infringe patents or that the patents are invalid. Besides having access to a previously closed market, these companies have a second incentive: the first generic firm to file its application (after the FDA approval) benefits from 180 days of marketing exclusivity; its only competitor would be the brand-name pharmaceutical company.
The brand-name companies, to maintain their exclusivity during the patent duration will typically challenge the generic firms' allegations; litigations will ensue between the two parties to evaluate the patent validity or infringement.

Because of the cost and the uncertainty of patent litigation, both parties will try to reach an agreement instead of a court decision. Two types of agreements exist:
• The first one without any compensation for the generic firms. They agree on the time of entry of the generic firm. Typically after the generic firm challenges the patent and before the expiration of it. Because there is no compensation, this type of settlements will not raise antitrust issue.
• The second type of agreement adds to the previous one some compensation for the generic firms. And this is considered as an antitrust practice.

These agreements have two main impacts:
• First they delay entry of generic firms. Besides, the FTC highlights in the study that: "agreements with compensation on average prohibit generic entry for nearly 17 months longer than agreements without payments"
• Secondly, because the competition is delayed, the prices remain higher for a longer period of time and it impacts the consumers (patients and the governments).

2. OPINION, REMARKS…

• In this issue, the inconceivable point for me is how a can patent be granted and then declared invalid or that a generic drug (identical to the brand-name drug) is not considered as a patent infringement. In my opinion, something is not right in the drug patent system. Is it because drugs and their applications are unpredictable beforehand?

• About the impacts of these agreements on the consumers, some argue that after the introduction of generic drugs, no significant rise in terms of drugs consumed was observed. That may be true but drugs are needed good: if a patient needs a drug he/she will buy it regardless of the price. Besides, in many countries, drugs are covered by social security (or another system). At the end of the day, the presence or absence of generic drugs will have no significant impact on the number of items sold but well on the cost supported by the different consumers. And in the current context of austerity and financial troubles, final consumers and governments try to reduce their health expenditure.

• Pay-for-delays should be banned in every industry not only in the drug industry not for social reasons but just because it violates one of the basic principles of our modern markets: free access and entry.

• Besides if a patent is granted it should be respected and the brand-name companies should enjoy from their exclusivity until the patent's expiration except in case of major health problem (agreements such as pay-for-delays will not happen). Of course it will have an impact on consumer but we must not forget that drug companies are not non-profit organizations. This patent is needed for them to cover at least part of the costs generated to produce the drugs. Or maybe another system of patent should be implemented: the time of exclusivity could be proportional to the cost supported by the companies.

Agreements such as pay-for-delays in the drug industry are agreements people are more sensitive to because of its welfare effects and

therefore reaching a consensus is tougher than in other situations.

See: "Pay-for-Delay: How Drug Company Pay-offs Cost Consumer Billions". http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. Federal Trade Commission, Jan. 2010. Web. 31 Oct. 2012.

Like: 0

REPLY

Paul Belleflamme 7 November 2012 at 13:35 #

Excellent summary!

REPLY

Sriram Vasireddi 7 November 2012 at 08:58 #

In my opinion I see this issue of The US passing a legislation in banning these Pay-for-Delay deals an extension to the Hatch-Waxman Act in their view. But what is more critical is that since the Generic companies were previously accepting these deals and have got nothing to lose in either case only time will find another solution in which a different form of Pay-For-Delay deal might arise.

What is more important for the US government or the European Union is that they have to scrutinize more the patent process and the way the patents are being filed rather than affecting the revenue models.. The big-brand innovator companies obviously would need incentives to innovate,It would be more advantageous if the governments can use their legislative powers to channelize the Innovator companies to innovate more by using other strategies like for example-encouraging Joint alliances between innovators and generic companies so that the reach is improved in emerging markets on a social level-GlaxoSmithKline plc (GSK) for example entered into a join alliance with an Indian Generic drug manufacturer-Dr. Reddy's Laboratories (NYSE: RDY) to develop and market select products across emerging markets outside India.

From the governments perspective,they might be doing this only because ultimately they are paying a majority of the medical expenses and to the pharmaceutical companies,but a review of the patent filings in pharmaceutical industry is far more important which is slightly different form the other industries as they involve clinical trials and the uncertainty being higher-the incentives to innovate must only be more

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Dr. Reddy's announces strategic alliance with GSK for Emerging Markets-http://www.drreddys.com/media/popups/jun15_2009.html

http://www.forbes.com/sites/brucejapsen/2012/07/30/no-matter-how-u-s-courts-view-pay-for-delay-brand-drugs-thriving-in-emerging-markets/

Like: 0

REPLY

Paul Belleflamme 7 November 2012 at 12:25 #

Interesting merger case.

REPLY

Aviral Shrivastava 7 November 2012 at 00:17 #

Under the Hatch-Waxman Act of 1984, the brand company pays the generic company not to challenge the patent that covers the brand company's drug, to stay out of the market, and to settle litigation.

Pay for delay settlement raise some critical questions. Patents are crucial for the pharmaceutical industry to invest in R&D and to encourage innovation. However, this is subject to the condition that the holder of patent will be protected against the infringement. It takes pharmaceutical companies many years to develop new drugs and a long time to recover the costs. The companies also consider the costs of litigation and the possibility that the patents will be invalidated. These settlements promote stability and thus innovation.

According to a study, in 2007, pharmaceutical companies invested about $60 billion in R&D. Of the approved drugs (one out of 5,000 on average) only about 20% to 30% could recoup their initial investment. The above figures highlight the importance of patent protection for innovation to continue and a suitable return on investment for brand companies.

A strong argument against pay-for-delay settlements is that they give pharmaceutical companies more exclusionary power than they

should have. A study by University of Houston Law School showed that as much as 45% of those patents reviewed by the court in 2009 were undeserved. Also, almost 95% of patents got their claims cancelled or changed when challenged in US Patent and Trademark Office.
At the same time, the high prices of brand drugs present significant challenges to the consumers, the government and the insurance companies.

Both the brand and generic companies seek to avoid Hatch-Waxman litigation because of the high costs and the uncertainty of the outcome of litigation. Thus they enter into the out of court settlements according to which the generic company agrees not to enter the market while the brand company pays the generic company. This practice benefits the companies but harms the consumers greatly. The loss to the consumers has been estimated to be ranging from $3.5 to $14 billion.

Anup Malani, in his article in Forbes' magazine talks that insurance prevents patients from being priced out of patented drugs. However, this is true only in the cases where a large portion of the population is covered under health insurance and does not bear the whole cost. In many developing countries, health insurance can be afforded by a very small proportion of the population. Many people are denied of crucial and life saving medical care in these countries because of non availability of generic drugs or the branded ones being too expensive.

He argues that the consumer is not affected because it is the government which is paying for the costs. It is to be noted that the government itself runs on the taxpayer's money. Increased expenditure on the branded drugs by the government eventually hits the consumer only.

As discussed in many articles and the comments mentioned above, it is difficult to come to a conclusion and draw a line regarding the benefits of Pay-for-delay settlements. The system granting patents should be made more rigorous such that the brand companies don't get away with only slight modification and charge higher prices. However, at the same time it should be noted that patents are currently the only effective measure to get the companies to innovate and get sound returns on their investments. Thus, for the benefit of the society in the long run, the companies should not be dis-incentivised to innovate.
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4. http://www.manhattan-institute.org/html/mpr_11.htm
5. http://www.forbes.com/2010/07/15/drug-patents-pharmaceuticals-opinions-contributors-anup-malani_2.html

Like: 0

REPLY

Paul Belleflamme 7 November 2012 at 12:23 #

Thanks for these precisions.

REPLY

Hadelin Rosseeuw 6 November 2012 at 21:49 #

In this comment, I will share my point of view on the striking "Pay-For-delay" deals that are occurring increasingly in the pharmaceutical sector. Afterwards, I will attempt to raise an alternative to those deals that would suit the pioneer, the generic producer and the consumers.
First of all, the Federal Trade Commission is considering such settlements as "anti-competitive and a violation of long-established antitrust laws" (1). In this sense, the "Pay-for-Delay" practice is to be prohibited as it prevents firms to sell drugs at a lower price. Given this practice deals with healthcare, one has to take into account that some drugs are essential to human being and, therefore, must be affordable for everyone, particularly when lives are at stake (e.g. HIV). Moreover, it has been measured by C. Scott Hemphill that consumers would lose more than $660 million in case the generic drug is delayed by one year (2).

However, I am convinced that a compromise should be reached concerning the time limit of delay as it enables pioneer to reap profits in order to recoup their huge investments and rewarding their innovative move. For this main reason, I believe it should benefit from a longer period of patent so that the incentive to innovate for these firms lasts. That said, the compromise should provide the best exit scenario to consumers and governments (public expenditures), i.e. with respect to consumer protection laws.

By the way, one has to bear in mind that some cooperation are allowed if the purpose target to improve the well-being of consumers and, therefore, needs tremendous investment in R&D such that a collaboration between firms is needed. Indeed, the share of the R&D's costs enables the firms to operate in a more efficient manner.

(1): http://judiciary.house.gov/hearings/printers/111th/111-105_50066.PDF
(2): http://articles.latimes.com/2011/may/10/business/la-fi-hiltzik-20110511

Like: 0

REPLY

Laura Ioana Bidea 6 November 2012 at 18:33 #

My analysis of the pay-for-delay deals, addressing and challenging some of the points raised before by my colleagues:

One popular argument goes that the pay-for-delay schemes may induce "brand" companies to continue investing in research and deliver new drugs on the market (which maybe would not happen absent the patent, due to lack of funds). On the other hand, however, we are talking about medicine. Peoples' lives may hinge on the availability and price of these drugs, and because they would attach a higher utility to buying them, a larger total social welfare is at stake.

It is also true that in a plethora of situations, it is not the patient that actually pays for the drug, but the health insurance company, like Malani also argues in his Forbes article. However, to the best of my knowledge, the insurances cover the more or less "basic" drugs, while the financial burden of the brand drugs, designed for more severe or rare illnesses falls on the patient. So in my opinion it cannot always be argued that the pay-for-delay deals do not harm consumers, since government does not always cover the medicine costs.

In the same vein, there is evidence that R&D costs might not be as high as claimed: it has been argued that bringing a new drug to the market costs around $1 billion, but new research shows that it could actually be much lower (around $55 million). Additionally, more and more points are being raised about the structure of the drugs market – firms have more incentives to medicines of little advantage and compete for market shares at high prices rather than develop accesible medicines with alternative funding sources (public ones). (http://www.pharmamyths.net/files/Biosocieties_2011_Myths_of_High_Drug_Research_Costs.pdf, http://www.slate.com/articles/business/the_customer/2011/03/the_makebelieve_billion.single.html). Also, a large part of the pharma innovations takes place in the publicly-funded research centres and not in the private laboratories of the drug companies, thus making the consumer pay basically two times, through the taxes collected and through the drugs price (http://www.amazon.com/800-Million-Pill-Truth-behind/dp/0520246705/ref=sr_1_1?ie=UTF8&s=books&qid=1299204443&sr=1-1).

In addition to this, drug companies can find ways around the fact that the ban on pay-for-delay settlements will diminish their revenues. More specifically, they can promote their drugs on rapidly growing emerging markets, where the supply of medicines has been low given that, for instance, the generic drug companies find it more expensive to expand on those markets. For instance, Pfizer, Abbott Laboratories, and Novartis set up a line of business, "established pharmaceuticals", which grew 4% worldwide, with the emergent markets largely driving this growth (http://www.forbes.com/sites/brucejapsen/2012/07/30/no-matter-how-u-s-courts-view-pay-for-delay-brand-drugs-thriving-in-emerging-markets/)

It could also be argued that the ban of the pay-for-delay deals could lead to a "natural" selection of the patents: the ones that are truly innovative will still stand, even if attacked in court, while the ones that are not valuable will end up on the competitive market. The theory also suggests that whenever the monopolists will feel threatened by entry (in our case, when the settlements are not possible), they will have even more incentives to innovate than when they are sheltered from competition. This argument bears one caveat however, that similar to market imperfections, courts and judges are also flawed, which is why the reasoning above might not hold water in all cases. Furthermore, litigations do imply significant costs and do not have a guaranteed result, which can make for an argument in favor of the settlements: if the deal will allow the generic entry on the market before the patent expiration, but after the entry that would have been possible by challenging the patent in court, settlements could be welfare-improving, since it saves the costs of litigation and the uncertainty attached to the court dispute. However, this scenario depends primarily on the features of the settlements (balancing the pros and cons for the court dispute and the settlement), which are largely at the whim of the companies and cannot be legally enforced.

The bottom line of the pay-for-delay deals is far from clear and multifaceted, such that it needs a very rigorous analysis before reaching any decision, but it could be that a more tailored solution, which takes into account the specifics of each case and that would dissuade the generic companies from agreeing to welfare-diminishing terms or smoothing their financial incentives to drop the patent challenges (http://www.nejm.org/doi/full/10.1056/NEJMhle1102235#t=article).

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Like: 0

REPLY

Paul Belleflamme 6 November 2012 at 20:26 #

Excellent addition to the debate. I'm really pleased with the quality of all your comments. Please continue the good work!

REPLY

Hecq Elise 6 November 2012 at 10:56 #

About monopoly's innovation, there are 2 views. On the one hand, Arrow said that monopoly would be less willing to pay a fixed cost to adopt new technology. And on the other hand, Richard Gilbert and David Newbery consider that monopoly can be threatened by entry and in this case, it must choose between adopting an innovation and allowing a rival to adopt it. Several papers have shown that the incumbent might loose his place as monopolist if he doesn't adopt the technology but the rival does. So, monopolist will pre-emptively patent before a rival. With the "pay for delay" deals, it permits to pharmaceuticals firms to conserve monopoly longer. It encourages the innovation of pharmaceutical industry.

Furthermore, theses deals also reduce the consumer's welfare because the prices of drugs are too high and during a long period. The pharmaceuticals industry plays a role in the public health issue. It's necessary to find a trade-off between the pharmaceutical industry and the public health, but this is quite complex. It's important to give incentives for innovation to big firms. But if a lot of people can afford their drugs because prices are too high too long, the consequence is less profits for big firms and so the total welfare is also reduced. Reduce the patent period is not a solution too, because we don't push big firms to innovate. And if there is no innovation, it also reduces the consumer welfare.

For the consumer, the government may help them to pay their drugs by reimburse a party of the drug fees. But, this kind of mechanism requires paying a health insurance and that is a cost for consumer too.

From the point of view of the law, recently (July 2012), the U.S Court of Appeals for the Third Circuit said that "pay-for-delay" agreements were anticompetitive. This is a consequence of the two lawsuits involving a pharmaceutical company Schering-Plough and two generic manufacturers Upsher-Smith and ESI Lederle (see the link : http://www.ama-assn.org/amednews/2012/07/30/gvsc0730.htm). However, deals might be presumed legal if there is evidence that the big pharmaceutical firm's purpose was not anticompetitive and that there are precompetitive effects. In addition, in the same time, other Circuit Courts had decided that theses deals were legal, as long as generics manufacturers were not paid to refrain from marketing a drug after the brand-name manufacturer's patents expired. So law on this point is not very clear. It shows that the situation of "pay-for-delay" is complex and the solution is not obvious.

But, since many years now, there is an increasing trend to use "pay-for-delay" agreements and Courts are more and more friendly with theses deals. In this respect, the recent Third Circuit decision may discourage the enthusiasm for theses agreements. Although, this court has a well-defined geographic domain, and this decision affect directly the firms, witch are situated in this specified geography (Pennsylvania, Delaware, and New Jersey). But it is possible that the effects of such decision go outside the court domain. If the big firms and the generics companies settle this kind of agreements, the consequences will be lower prices, witch are good for consumer. But if big firms have to settle all the patent infringements with lawsuits, it also creates litigation costs that consumers will have to pay a day and consumer won't be happy, too, if firms have fewer incentives to innovate. Moreover, delays to litigation may get longer the access to drug.

So I think that the solution is not easy to find. Ban "pay-for-delay" is not the solution, because firms will always find a way to reach what they want.

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http://www.nejm.org/doi/full/10.1056/NEJMhle1102235
http://www.forbes.com/2010/07/15/drug-patents-pharmaceuticals-opinions-contributors-anup-malani.html

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REPLY

Paul Belleflamme 6 November 2012 at 12:44 #

Thanks for these details.

REPLY

Peters Pauline 6 November 2012 at 10:30 #

I will try to give my opinion on this sensitive issue. As Eleanor M. Fox said, an antitrust expert and professor at the School of New York University Law School, it is a case of collusion. Indeed, there is agreement between two competitors. The stakes are high on both sides.

Generally, the collaboration takes place as follows: There is already a patented drug and someone comes up with a generic drug, which is equivalent to the existing drug. The manufacturer goes to the FDA (Food and Drug Administration) for the sale, claiming that the patent is invalid. Instead of spending a lot of money to defend his patent, the patented pharmaceutical company proposes to pay its competitor to keep its drug on the market only for a certain period.

According to Posner, there are three reasons why firms need this mechanism. First, new drugs are very expensive. Second, manufacturers of branded drugs are not able to earn enough money from their inventions because it takes years of study to innovate and bring new products to the market. Third, for the generic companies, it does not cost them expensive to copy drugs once someone has already invested in it. Without a patent, manufacturers of branded drugs are not included in their fees.

This agreement between competitors is not beneficial to the consumer. This makes sense since that generic drugs cost less than

branded drugs. And therefore more generic drugs are slow to be placed on the market, consumers have to pay more for branded drugs. As Mr. Naes, CEO of the Generic Pharmaceutical Association (a trade group in Washington), said, generic drugs have reduced the cost of drugs Americans.
It should therefore find a good compromise to find the "perfect" arrival of generic drugs, that the company has repaid its costs and the consumer has the faster the generic drug.

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REPLY

Alexander Himbert 5 November 2012 at 23:50 #

The key to understand the heated and intense debate about the pay-for-delay settlements in the pharmaceutical sector are the large externalities on social welfare these settlements bring along. As the U.S. Federal Trade Commission (FTC) argues (Leibowitz, 2009), the cost of prolonged entry by generic firms into the market to American consumers is estimated at around 3.5 billion $ per year. Such an amount alone would already provide a strong argument to question these settlements. If one takes into account the fact that in this case the costs to the consumer are not necessarily paid by the individual consumer that uses the drug, but by the health-care system (where the contribution of people with low income won't cover the use of expensive drugs and will therefore require either redistributions via higher contributions of people with higher incomes or losses to the insurance system), the pay-for-delay system becomes even more distortionary. In this sense I cannot agree with commentators that see a "win-win-situation" for the patent holder and the generic firm as it fails to account for the large dimension of social welfare distortions involved in the issue.

However, one has to take a look at the rationale behind the existing patent system in the context of the pharmaceutical sector. Generally spoken, a patent needs to cover the cost of R&D and promote innovation. As Malani's commentary in the Forbes journal points out, this definition is already problematic to describe the pharmaceutical sector. In this sector, not only innovators with novel ideas need their costs to be covered, but every drug – novel or not in its approach – needs to be tested before it can be marketed. The costs of these tests can be quite significant and therefore need to be covered somehow, even if the drug is not "innovative", as drugs are information goods with low costs of reproducing for imitators (Pluta, 2010). In this sense, we see that there is a need for some form of protection, the remaining questions is whether the current system is the most effective in doing so.

Besides the social cost to the consumer in the form of unnecessary high prices a second problem of the existing are the incentives for innovation it creates for the involved firms. For the generic firm the incentive becomes "be the first to be paid" instead of "first to innovate" (Leibowitz, 2009) if the expected increase in profits is smaller than the payment for delay offered by the patent holder. In my opinion, it is problematic to apply the concept of a monopoly threatened by entry in this setting. In this model, the monopolist usually faces a decision between letting the entrant innovate or innovate himself. This is not the case when pay-for-delay settlements are allowed: The monopolist just pays to hinder the innovation, so no innovation takes place at all. This becomes even worse when keeping in mind that the willingness of the incumbent to pay the generic firm for delayed entry is highest when the patents are weakest. By this, a weak patent for a probably not "novel" drug is used to prevent generic firms from decreasing the price to the consumer (Leibowitz, 2009). What should be obvious by now is that the current patent system is socially inefficient because it a) causes huge costs for consumers and the health care system and b) potentially slows down the innovating process.

However, of the few theoretical models investigating this issue, a surprisingly large number still argues in favor of pay-for-delay (example: Gratz, 2012). The reason for this lies in the limited scope of alternatives these models discuss. The key assumption in favor for pay-for-delay usually are the high costs for both firms of lawsuits to challenge patents combined with the probabilistic and therefore uncertain outcome of the rulings and the potentially long time range that is taken by the process. This is true only as long as one takes a patent system as given. If one on the other hand considers are more reward oriented system, these costs diminish or disappear completely, while it would still be possible to cover the costs of R&D and testing new drugs (and maybe even more accurate as the reward could just exactly cover the cost while a patent does not). The question then becomes if there is a central planning institution capable to pay the reward system. As in the case of the pharmaceutical sector, costs are covered at least in parts by a health care system that the state supervises in some form (varying from country to country of course, but the principle remains), and the potential gains for the healthcare system are very large in the U.S., this could very likely be the case.As the cost of R&D in the sector is still by far higher than 3.5 bn $ (Forbes, 2012), the rewards might only apply to the discussed cases of weak patents, but as these are the ones most likely affected by pay-for-delay, this would still be a step into the right direction.

My idea for this reason would be to switch the debate from being simply focused on the existing patent system to considering the alternative of a system of rewards, where the potential reward for drugs that are novel of course would be higher than for non-novel drugs that just require to be tested, while even those non-novel drugs would be covered sufficiently. By this, one could a) decrease the prices to the consumers by a large share and improve social welfare b) change the incentives for generic firms back to "first-to-innovate" while c) still covering the cost of R&D for large firms.

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Like: 0

REPLY

Paul Belleflamme 6 November 2012 at 08:27 #

Interesting propositions. To be discussed.

REPLY

Adriana Guth 5 November 2012 at 09:30 #

With this comment I would like to address some of the issues around the pay for delay debate and I can hopefully provide you with some new insights to the discussion.

Before delving into arguments for and against "pay for delay" I would like to sum up some facts about the pharmaceutical industry and their customers. Inevitably they do have very high R&D expenses. It is a regulated market, prices and seller of prescription drugs are fix. The consumer is not the decision maker, the doctor prescribes the drugs. In addition to that the actors are not price sensitive because in most cases their costs are covered by the health insurance.
The pharmaceutical industry is dominated by a few companies, most of them located in the United States, which are ranked at forbes global 2000. There is Pfizer (34), Johnson&Johnson (57), Merck & Co. (80) and Abbot Laboratories (127) (1).
Nevertheless, the entrance of generic drugs in the market has a great effect on the brand-name producer as the following example will underline. When a generic product for one of the mostly sold antidepressants such as "Prozac" was available in 2001, the revenues of Eli Lilly & Co. dropped from 2 billion to 500 million (2).

The deals for "pay for delay" where brand –name pharmaceutical companies pay generic manufacturers to refrain from making a drug after the patents expires are definitely anticompetitive. It is simply a division of monopoly profits between patent holders and potential competitors in order to protect the monopoly price.
Douglas Clement provides in the article "creative disruptions" (3) empirical and theoretical evidence that nations should support competition in order to grow economically.
He makes clear – as we have calculated in our group assignment – that monopolies not threatened by entry are less likely to innovate. Adopting a new technology will lead to switchover costs and "greater market power will mean higher prices on those lost units of output and hence a reduced incentive to innovate" (3).
But at the same time, a monopoly threatened by entry is enormously willing to invest and innovate, because they have to calculate the risks of having the innovation for themselves or handing them over to their competitor.

Summing up these results and their consequences, pharmaceutical industry should be threatened by entry of generic manufacturers and therefore I think it is the right decision to abandon "pay for delay" deals. It is just a means to divide monopoly outputs without generating any surplus for the consumer.
Anup Malami (4) was arguing that in case of a health care system, the total amount of demand will not rise after launching a generic drug, but without doubts the costs will reduce. The study of the European Federation of Pharmaceutical Industry and Association (EFPIA) from 2012 (5) shows, that the percentage of generics in pharmaceutical market sales range from 8,4% (Spain) to 56,4% (Poland). Identifying Poland, Serbia and Lithuania (56,4-50%) having the highest consumption of generics leads to the conclusion that there is a connection between national income and national healthcare system, and therefore patients and doctors can act price sensitively.

Due to an aging population and problems financing NHC all European countries should take this chance to reduce their costs without reducing quality.
NO matter which decision the European Commission will make, "pay for delay" has a huge impact on rights of patent holders to exclude competitors, relationship between generic and brand, name manufacturer, degree of market competition and consumer prices.

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Like: 0

REPLY

Paul Belleflamme 5 November 2012 at 13:57 #

You did indeed provide the class with some new insights to the discussion. Thanks.

REPLY

LIU Manjing 2 November 2012 at 11:22 #

Before giving comments on « pay-for-delay settlements », it is interesting to understand the background of this issue.
The Hatch-Waxman Act of 1982 has legalized entry barriers against generic drug producers, i.e. the generic producer couldn't enter the pharmaceutical markets if its product infringed on an innovator's drug patent.
The « pay-for-delay settlements » has made the postponing of the entry for a generic drug possible. The agreement between branded and generic groups should let them to achieve a "win-win" situation, then the branded firm will pay for a delayed entry, in other words the generic firm will share a part of the benefits from the brand's monopoly profits.

It is not pertinent to take just the gain of the industries in account, than consumers suffer from this agreement, which postpones their savings from lower generic drug prices.

In return, should we prohibit « pay-for-delay settlements », which lead the banded firm to benefit from a longer monopoly benefit or maybe reduce the duration of a drug patent? Firstly, we should understand that the two suggested methods have an important effect on the incentive power for pharmaceutical innovations. If we reduce the duration, during which the firm plays the monopoly role, it will have a horrible impact on our society, because the gain of an innovation will be seen as not "great" enough and the branded drug industry will not innovate anymore. Secondly, no innovation means also no research for new drug and this lead once again to a loss for consumers.

From my point of view, consumers are playing the "victim" role in any case, and therefor the government should protect them and regulate the pharmaceutical market to achieve an efficient situation. One possible solution will be to set a price cap for a drug according to the production cost and pay extra money for any innovation effort. Another solution would be to pay subsides to firms in order to push them to innovate.

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Like: 0

REPLY

Paul Belleflamme 5 November 2012 at 08:45 #

Good analysis.

REPLY

Johan Fredrik Hillveg 1 November 2012 at 14:57 #

Before we all judge the big brand-name players for paying generic companies to postpone products in "back-pocket deals", it is important to understand why these payments come to light.

As the CEO of the Generic Pharmaceutical Association, Ralph G. Neas, states: "These agreements have never delayed the availability of a generic drug past the expiration of a brand-name drug's patent" (1).

If pay-for-delay settlements were made active after patent expiration, clearly they would violate the concepts of free trade. However, assuming Neas is right, this is never the case. Then the real issue (again) revolves around the patent breadth. As long as a patent is proved invalid in court, the generic producers are free to play in the big league. So whenever a patent infringement may arise, the incumbent firm is facing the dilemma: Should it accommodate, go to court or "pay-for-delay" to prolong its monopoly situation?

Obviously, earlier accommodations hurt new product-development. If generic companies enter too soon, the incumbent firms will bleed profits. Having in mind that the average cost of bringing a new drug to market is an astonishing $4 billion (AztraZeneca has spent $12bn for every new commercialised drug!), a long patent duration is needed for product innovation in the pharmaceutical industry (2).

Also, sharing the monopoly profits by pay-for-delay deals can be seen as a far more cost-efficient way of solving the patent breadth issue than enduring a time consuming and costly trial. Banning these agreements is thus likely to lead to more patent trials and more uncertainty for the innovating companies. This means less innovation in what to me seems to me like an already unsustainable industry (given the abnormally high R&D costs per product).

Patents are means to increase the long-term dynamic efficiency at the cost of short-term static efficiency. So how do these agreements

really affect static efficiency? John Leibowitz, the chairman of FTC, claims that pay-for-delay deals annually cost American consumers $3.5 billion (3). But as professor Anup Malani at the University of Chicago Law School highlights: Health insurance plans requires the consumers only to pay a co-pay of the drug. It is the government that takes most of the bill (4). In fact, modern research shows that the quantity sold after a drug goes generic does not even rise (5).

So in fact, by keeping these agreements legal, the government indirectly subsidize drug innovation through higher prices. And given the fact that the generic companies agrees to these pay-for-delay deals, the smaller players do not seem to suffer either (otherwise they would not have accepted the deal in the first place). Having this in mind, it seems to me that pay-for-delay may be "a necessary evil" in order to sustain new drug-innovations in the pharmaceutical industry.

However, the world is not always as simple as the books want us to believe. It is important to note that the monopoly party does not always end when a patent expires. In real life, Pfizer, Abbott and Novartis still thrive on old medicines (6). Obviously, there is a great value of having a safe drug with a solid reputation worldwide. How much this trait affects the pay-for-delay decisions is for someone else to decide.

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REPLY

Paul Belleflamme 5 November 2012 at 08:38 #

Very thorough and well-balanced comment. Thanks.

REPLY

Van Frausum Derrick 31 October 2012 at 23:41 #

Indeed, the issue is complex and it's not only about the pay-for-delay settlements. As the EU competition commissioner Neelie Kroes has said, "something is rotten in the industry."

In order to earn the most profit, the pharmaceuticals companies use all kind of tactics. In particular, they play on the weaknesses of patent systems: the brand-name firms to create barriers to entry and the generic group to attack the patents of the latter.

The "pay-for-delay" deals are undoubtedly the epitome that the pharmaceutical industry isn't running true. By pushing generic drugs makers aside, they allow the big firms to keep their prices very high. As Marta Ripamonti has already said in her post, a study by The Federal Trade Commission (FTC) show that they cost Americans 3,5 billion USD a year. And in Europe, according the European Commission, the delay between expiration of patent for a branded drug and launch of the associated generic – generally 7 months – costs patient 4,3 billion USD a year.

So, the repercussions on the cost of health care are not to be taken with a pinch of salt.

Despite these figures, the big firms claim "pay-for-delay" settlements benefits the consumers. Really? Even though, this is to defend their anti-competitive behavior, I can't say they are completely wrong. Without these arrangements, they would spend enormous time and money in courts, and these could affect the price of drugs in the wrong direction. However, even if the drug prices don't rise, the current prices will continue to be high during a longer period to the detriment of consumers.

More than the possibility of enduring high patent-litigation costs, the reason the big companies hasten to strike deals with generic drug makers is that the stakes are high.

I found a case in 2006 that is particularly speaking: after a failed settlement between Bristol-Myers Squibb (branded drug producer) and Apotex (generic producer), the latter launched their medicine at a cost much less than the branded one. In 5 days, Bristol-Myers Squibb had lost more than 500 million in sales, before finally winning the market exclusivity during the patent lawsuit.

In the U.S, these pay-for-deals are – in a way – the answer to the Hatch–Waxman Act of 1984 (For more information, see http://www.cptech.org/ip/health/generic/hw.html). Its main goal is to encourage the entry of cheap drugs. It allows an exclusivity of 180 day to the first generic firm that challenges patents on a specific drug and gets to sell its generic version.

This act has increased the uncertainty for the patent holders to be properly protected. Hence if their patents are more than likely to be challenged and invalidated, the big firms are less incited to innovation.
Obviously, the U.S. federal law needs to be revised.

And what about in Europe? With the probable arrival of a unified European patent and litigation procedure, the generics firms will have more ability to contest patents of branded companies because it is easier to dispute one patent for the whole EU market instead of

patents in each country.

Although the generic groups offer their drugs at a lower price and benefit the well-being of consumers (at least in the short term), I just don't feel right about it. They make the health care more accessible but not in a fair/legal way. Definitely, they take advantage of the efforts of the brand-name drug manufacturers in R&D and thus in cost.

To conclude, I think both sides are to dispraise. And in a sector vital to the well-being of society, it appears very important to bring more clarity in the legal and common practices of the industry.

As for "pay-for-delay" deals, I'm not convinced that they are for consumers' sake, as the big firms say it. But I know resolving the conflict between the profits of companies and the well-being of society is too difficult to hope that just banning "pay-for-delay" agreements is THE solution. You need an adequate policy of innovation as well, one that reduces the prices of drugs without altering incentives for innovation/to undertake R&D.

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REPLY

Paul Belleflamme 5 November 2012 at 08:48 #

Rigorous argumentation: very good!

REPLY

LOUIS Pauline 30 October 2012 at 20:30 #

The pharmaceutical industry is characterized by high fixed costs for the invention and low marginal costs for the production. So, fixed sunk costs are an important component in the pharmaceutical project's budget. As a result, a producer must have a long patent in order to provide him an incentive to develop a new drug.
Another advantage in favor of the deal 'pay for delay' between the pharmaceutical dominant firm and the entrant is the duplication of fixed costs. If we promote the increase of pharmaceutical rivals; the R & D costs, testing costs for clinical trials, etc… are duplicated. Under these conditions, a central planner can be profitable for everyone. However, we must remain vigilant if this monopolist owns critical private information to assess the relevance of the drug's price. The inventor could use his monopoly to charge unjustified high prices. This would be harmful for the consumers' welfare. In fact it is already the case nowadays; some drugs are inaccessible for many consumers due to their prices. In addition, the presence of a patent reduces the degree of innovation, which is harmful to society.

Moreover, profit per firm declines with an additional entrant. It is profitable for the monopolist to remain the only one on the market if he wants to maximize his profit. Indeed, prices fall with the competition; but the elasticity of demand is very low in the pharmaceutical sector. This means that a decrease in prices not necessarily implies an increase in sales. The market size is fixed because products are relatively old by the time their patents expire; the brand has extended the market as much as it can. So, the drop in price due to the introduction of new firm means smaller quantity for each one and does not increase total quantity sold. The arrival of generics firms must be avoided at all costs in this sector (more than elsewhere) because the supply of cheaper generics drugs would grab a large portion of the demand for brand drugs.
Another advantage in favor of a long period of protection is the characteristic of the patent. Contrary to regular industries, the patent is a real decisive incentive. It is granted before the research to protect investments. Without this one, the firm would not develop a drug because it requires a lot of expensive clinical trials before being able to launch the product and receiving the first revenues.

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Like: 0

REPLY

Paul Belleflamme 5 November 2012 at 08:51 #

Thanks for the useful references.

REPLY

Marta Ripamonti 24 October 2012 at 13:39 #

The problem of "Pay-for-Delay"has been discussed for many years, but the solution of the problem, as expressed above is pretty trivial; in the next lines I will purpose my point of view taking into account both the economic theories and the fact that here we are dealing with drugs, that is a fundamental issue for my personal perspective.

Resting on R. J. Gilbert and M. G. Newbery "Preemptive Patenting and the Persistence of Monopoly" paper, it could be assert that even if the incumbent firm adopts a preemptive behavior with respect to the possible substitute technologies of a rival, this doesn't ensure an higher returns in the future. This implies that there exists other ways for deterring a rival's entry and make higher profits (i.e. a faster investment made by the incumbent arises the possibility for it to accumulate capacity and consequently capital for deterring the rival; at the same advertizing is seen as a way for prevent a second firm presence in the market).

Linked to this discussion that is referred to all kind of products in the market, what I think, is that the prohibitive actions that the European Union and the U.S. are taking, concerning the "Pay-for-Delay" drugs problem, are the right ones. First of all because we are dealing with a particular type of good and innovation that are drugs, which are related with society health, that is one of the most important individual rights, which have to be preserved. The "Pay-for-Delay" system addresses to a very high cost imposed to the society for waiting the generic drug; the FTC (Federal Trade Commission) in a 2010 report (http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf) has estimated a cost equal to $3,5 billion per year for this uncompetitive behavior, pushed by monopolistic branded drug companies.

Following my thought, a second related problem is the following one: an higher cost of generic drugs comes to a lower access for society to the consumption, that leads to a decreasing consumption and lower profits. Taking into account and having in mind that each society has a different need of drugs (depending on the level of development and health condition among nations), the restrictions to the consumption imposed by the "Pay-for-Delay" deals, could, in a long-term perspective, influence the healthy degree of society. This could increase the public health expenditure for a State and become a huge problem that a Government could not be able to manage.

Reasoning in a long-term view, avoiding the problem of "Pay-for-Delay" addresses to a more healthy society – because people are able to buy drugs, being the generic ones -, that comes to a lower public health expenditure; what the Government saves from this public expenditure, could be used to finance and boost the innovation of the monopoly drugs producer.
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REPLY

Paul Belleflamme 25 October 2012 at 06:45 #

Thanks for the references.

REPLY

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