

PATIENT'S ACCESS TO PILLS: FIGHT BETWEEN GENERIC AND BRAND-NAME DRUGS CONTINUES

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I. INTRODUCTION

Douglas William Jerrold rightly said – “A pill that the present moment is daily bread to thousands.”¹ In this modern era, the most valuable invention for mankind is the invention of a medicine which has helped in increasing human life expectancy and millions of lives are thus saved. Drugs and medicines account for a vital and substantial share of healthcare and economic prosperity of any country. On the other hand, it is noted that health and drug policies over the years tend to serve corporate interests rather than public health. In view of these developments, access to healthcare and to some particular medicines, has suffered a serious setback in recent years.

For instance, in 1980 only about 13% of the total drugs sold in U.S.A. were generic, now it is closer to 70% (this figure increases when patent protected drugs are taken out of the equation).²

In any major drug market, one can find that, the better the medicine, the higher its cost is. Every patient needs access to these better medicines which generally belong to the cadre of “Branded Drugs”. The costs involved in the invention and development of new “Branded Drugs” prompts the innovator company not to sell its drug at a cheap price because of the heavy cost, time and materials involved in it with respect to Research and Development.

On the other hand, generic manufacturers sell the same drug at a very low price which is generally affordable by everyone, at a rate which is sometimes as low as one-fourth the innovator's rate. Consumers receive benefits from generic drugs because they are less expensive, granting a better quality of life to consumers with limited income.³ But these generic

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1. DOUGLAS WILLIAM JERROLD, *THE CATSPAW* Act I, Scene I.
2. Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, Jul. 1998. <http://www.cbo.gov/doc.cfm?index=655>.
3. To take an example, as of 2001, the brand-name drug Vasotec, which is used to treat hypertension and congestive heart failure, costs \$180 for a one month supply, while its generic equivalent only cost \$55. Additionally, a ninety-day supply of Tagamet, an ulcer medication, costs \$135, while the generic equivalent Cimetidine only costs \$20. Wayne J. Guglielmo, *Prescription Drugs at Bargain Prices*, NEWSWEEK, Apr. 23, 2001.

manufacturers can launch their generic versions in the market only when the “patent term” of the innovator’s drug expires or the validity of the patent is challenged by the generics or the generics version is launched in the market without infringing the patented drug.

As the prices of branded prescription drugs rose astronomically and costs of prescription medicines were of great concern to many people, especially the growing population of senior citizens,⁴ many citizens and politicians pushed for legislative or regulatory strictures to increase access to more affordable generic alternatives.

Therefore, as the law changes with the needs of society, a change was made to the Patent laws that assured a sort of balance between the increasing access to cheaper generic drugs and ensuring the continued development of new drugs by pharmaceutical companies through the preservation of strong patent rights⁵

The Drug Price Competition and Patent Term Restoration Act, 1984⁶ commonly referred to as “Hatch Waxman Act”⁷ of the United States reflected this change, and was enacted to achieve the important balance between generic manufacturers of the patented drug and drug innovator companies.

This legislation authorized the Federal Food and Drug Administration (hereinafter FDA) to approve generic drugs⁸ upon the manufacturer’s submission of proof of bioequivalence.⁹

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4. Laura J. Robinson, *Analysis Of Recent Proposals To Reconfigure Hatch Waxman*, 11 JOURNAL OF INTELLECTUAL PROPERTY LAW 47 (Fall, 2003).
 5. For those unaware, a patent is a kind of intellectual property right (IPR). It allows rights (including exclusive manufacturing and marketing rights) pertaining to an object (product) and/or a means (process), with a view to reward the invention of the inventor. A “product patent” allows rights (including exclusive manufacturing and marketing rights) relating to the object, while a “process patent” relates to the means by which the product is derived. A product patent grants more benefits to the owner as no one can, by any means, produce that product without the consent of the patent holder. S. Panchal, *Just what is a Patent?* Apr. 6, 2005. <http://www.rediff.com/money/2005/apr/06patent.htm>.
 6. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of 21 U.S.C., 35 U.S.C., and 42 U.S.C.)
 7. The Hatch-Waxman Act, named for the two sponsoring Congressmen, was enacted into law in 1984. Representative Henry Waxman began his drive to institute pharmaceutical patent reform in the summer of 1983. Senator Orrin Hatch assisted Representative Waxman by sponsoring the legislation in the Senate. Alan D. Lourie, *Patent Term Restoration*, 66 JOURNAL OF THE PATENT & TRADEMARK OFFICE SOCIETY 526, 533 (1984).
 8. A generic drug is identical, or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies. <http://www.fda.gov/cder/ogd/#Introduction> .
 9. “Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and

Prior to the Hatch-Waxman Act, in order to obtain FDA approval, manufacturers of generic drugs were required to conduct the same clinical tests as manufacturers of new, brand-name drugs.¹⁰ The rigorous requirements for FDA approval narrowed the generic drug manufacturers' profit margin and stifled their growth, inhibiting consumer's access to affordable medicine. Thus, the Hatch-Waxman Act marked the dawn of the generic drug era.

Object of the Hatch Waxman Act

The dual purposes or the main object behind the Hatch-Waxman Act was to reimburse pharmaceutical patent holders for time lost due to the long review period needed to achieve FDA approval and to encourage generic drugs to enter the market by enacting procedures that expedite and incentivize their introduction.¹¹ However, several provisions of the Act have been abused time and again which has impeded the designed effect of higher availability of generic drugs.¹²

Historical background to the act

This Act was necessitated by the following observations:¹³

1. Dearth of generic drugs:

Somewhere in the year 1962 it was observed in the U.S.A. that out of the 150 'off patent drugs' in the market, there were no generic drugs¹⁴ because generic companies simply would not spend the time and money doing the clinical trials to get to the market. Owing to the burdensome measures

their bioavailability (rate and extent of availability) after administration in the same molar dose are similar to such a degree that their effects, with respect to both efficacy and safety, can be expected to be essentially the same. Pharmaceutical equivalence implies the same amount of the same active substance(s), in the same dosage form, for the same route of administration and meeting the same or comparable standards." Donald J. Birkett, *Generics - equal or not?* <http://www.australianprescriber.com/magazine/26/4/857/>.

10. A manufacturer of a new drug can file an application for FDA approval after completion of required clinical trials, if the data support the safety and effectiveness of the compound. These applications typically are 100,000 pages or longer and include all the data gathered during development and in clinical testing. The FDA is legally allowed six months for review of the application, however, the average new drug application takes 30 months for review. See 21 C.F.R. § 312 (2007).
11. Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2000)); Muris Statement <http://www.ftc.gov/os/2002/10/genericstestimony021009.pdf>.
12. John R. McNair, *If Hatch Wins, Make Waxman Pay: One-Way Fee Shifting As A Substitute Incentive To Resolve Abuse of the Hatch-Waxman Act*, UNIVERSITY OF ILLINOIS JOURNAL OF LAW, TECHNOLOGY AND POLICY (Spring 2007) <http://www.jltp.uiuc.edu/archives/McNair.pdf>.
13. Parikshit Bansal and Anand Sharma, *Generic Drugs and Their Approval - Part I of II, Jul. 25, 2005*, <http://www.ipfrontline.com/depts/article.asp?id=4477&deptid=4>.
14. *The Hatch-Waxman Act: Tool for Approving Generic Drugs*, TIFAC BULLETIN, Feb. – Mar., 2004, <http://pfc.org.in/fac/feb04.pdf>.

involved, manufacturers were simply blasé to take up manufacture of these, even though these were cheaper.

2. Elusive regulatory procedures:

Most of the generic drug manufacturers refrained from manufacturing drugs due to the infeasible and un-scientific method by which the regulatory authorities viewed the drug approval process and insisted upon proving the obvious.

3. Denial of cheaper drugs to patients:

Generics were required to demonstrate the safety and effectiveness of their drug products through several clinical trials.¹⁵ Therefore, if a generic drug manufacturer wanted to market a drug after the innovator's patent had expired, that manufacturer would have to repeat extensive clinical trials to prove the drug's safety and effectiveness to the FDA.¹⁶

Owing to the difficult procedures insisted upon by regulatory authorities, drug companies avoided wasting time and money on clinical trials of generic drugs; therefore, the loss was faced directly by poor patients.

II. ESSENTIAL ELEMENTS OF THE HATCH WAXMAN ACT

The enactment of the Hatch Waxman Act created a balance between the innovator drug company and the generic manufacturer of the drug. The three essential elements in the Hatch Waxman Act were:

- 1. Experimental Use Exception** - The new law permitted a generic drug company to begin the testing required for FDA approval while the pioneer drug company's patent was still in force and shortened the period needed to obtain generic drug approval by eliminating the need for safety and efficacy data.¹⁷
- 2. Patent term Extension**- Patents are granted for a period of 20 years,¹⁸ however, it is often less than 20 years because patents, especially

15. Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA JOURNAL OF LAW AND TECHNOLOGY 389 (1999).

16. Joseph P. Reid, *A Generic Drug Price Scandal: Too Bitter a Pill for the Drug Price Competition and Patent Term Restoration Act to Swallow?*, 75 NOTRE DAME LAW REVIEW 309, 314 (1999).

17. "It shall not be an act of infringement to make, use, offer to sell, or sell ... a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs ..."35 U.S.C. 271(e) (1).

18. The period of market exclusivity when the product is actually on the market (without generic competition)— is generally calculated by subtracting the number of years it took to receive

for prescription¹⁹ drugs, are typically obtained prior to marketing. Patents on drug products are typically conferred very early in the development process²⁰.

Before a drug can be marketed in the U.S., it needs to be approved by the U.S Food and Drug Administration as safe and effective. Therefore, many years of additional research and clinical trials was required to obtain FDA approval to market the drug and the time it took for FDA approval process also “counted against” the drug’s patent time clock which means that this period ran concurrently with any patent term for the drug. Thus, the regulatory review period usually eroded much of the patent term.

The Hatch Waxman Act provided a time extension for patents to make up the drug testing and approval time.²¹

3. Abbreviated New Drug Application (ANDA) filing: Under this new law, there is also a provision to challenge the validity of the issued patent, thereby allowing Generic Manufacturers a route into the market. The validity of the patent can be challenged through Paragraph – IV and most of the challenges to the patent validity mostly arise from the Indian Generic manufactures by filing Paragraph – IV. The Act provides that the generics can enter the market by either of the following ways as mentioned below:

The generic companies can make any one of the four certifications for each Patent. This certification shall state one of the following:

final FDA marketing approval from the date the patent was filed (not the date the patent was granted). Robin J. Strong, *Hatch-Waxman, Generics, and Patents: Balancing Prescription Drug Innovation, Competition, and Affordability* http://www.nhpf.org/library/background-papers/BP_HatchWaxman_6-02.pdf.

19. A “prescription drug” is a licensed medicine that is regulated by legislation to require a prescription before it can be obtained. The term is used to distinguish it from over-the-counter drugs which can be obtained without a prescription. Prescription drugs are generally authorized by veterinarians, dentists, optometrists, and medical practitioners. http://en.wikipedia.org/wiki/Prescription_drug.
20. Patent is granted by the U.S.P.T.O. (United States Patent and Trade Mark Office) but approval is needed from FDA to market the drug so this process takes quite a long time.
21. The extension term for a pioneer drug is equal to one-half of the time of the investigational new drug (“IND”) period, running from the time in which a pioneer can begin human clinical trials plus the time during the NDA review period. However, if the patent was issued after the date of enactment or if the patent was issued before the date of enactment and no clinical testing had been conducted, the extension cannot exceed five years. If the patent was issued for a drug before the date of enactment and clinical testing had begun, it was considered a pipeline drug that could not obtain an extension exceeding two years. The reason for this distinction was “to encourage the research and development of future products. All products which had not yet undergone testing or review by the Food and Drug Administration were judged to be appropriately eligible for the full five years of patent extension.” Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD AND DRUG LAW JOURNAL 187 (1999).

Paragraph - I: A Paragraph - I certification is made when the innovator has not made the required patent information available in the “Orange Book”.²²

Paragraph - II: A Paragraph - II certification is appropriate when there is a patent listed in the Orange Book, but it has expired. The Abbreviated New Drug Application (ANDA)²³ applicant simply has to certify that the patent has expired, and provide the patent number and the date on which the patent has expired.

Paragraph - III: A Paragraph - III certification acknowledges that there is a patent that has not expired and that the “Abbreviated New Drug Application (ANDA)” applicant does not plan to market its product prior to the expiration of the patent.

Paragraph IV: A Paragraph - IV certification signifies that the ANDA applicant plans to challenge one or more of the listed patents. The ANDA holder hence claims that the patent is invalid, unenforceable, or, will not be infringed by the manufacture, use, or sale of the generic product. A generic applicant makes a Paragraph - IV certification only when its intention is to market the drug product prior to the expiration date of the patent.²⁴

When any generic company files Paragraph I or II certification, the Food and Drug Authority of the U.S.A. may approve its ANDA immediately.²⁵ While the Food and Drug Administration (FDA) may approve a Paragraph - III certification filed by an ANDA holder, anytime after the

22. Orange Book - The Hatch-Waxman Act allows an NDA (New Drug Application) holder, purportedly the original pharmaceutical company that invented the drug, to list its patent in what is called “Approved Drug Products with Therapeutic Equivalence Evaluations” or “the Orange Book.” The Orange Book is something that the Food and Drug Administration keeps. Once those patents are listed in the Orange Book, a generic company that would like to market the same drug must assert that those patents in the Orange Book are somehow invalid or not infringed by what the ANDA filer plans to do. <http://www.law.washington.edu/CASRIP/Symposium/Number7/1-Borecki.pdf>.

23. ANDA - Abbreviated New Drug Application - The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the Hatch-Waxman Amendments) created section 505(j) of the act (21 U.S.C. 355(j)). Section 505(j) established the ANDA approval process, which allows a generic version of a previously approved innovator drug to be approved without submission of a full new drug application (NDA). An ANDA refers to a previously approved new drug application (the “listed drug”) and relies upon the agency’s finding of safety and effectiveness for that drug product. Innovator drug applicants must include in NDA information about patents for the drug product that is the subject of the NDA. FDA publishes this patent information as part of the agency’s publication “Approved Drug”. http://www.fda.gov/cder/about/smallbiz/FR_generic_exclusivity.htm.

24. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, July 2002. <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

25. 21 U.S.C. § 355(c) (3) (A).

patent's expiration date²⁶ but the implications of a Paragraph - IV certification are not nearly as simple as the above three certifications. A generic company makes a Paragraph - IV certification when it does not want to wait for the expiration of the innovator companies' patent rights before it begins to market its own generic version of the drug instead, it alleges that it is justified in early market entry because its drug does not infringe the innovator's patent or because the patent is invalid.²⁷

III. BENEFITS AND LOSSES TO THE GENERIC MANUFACTURERS AND THE INNOVATOR COMPANIES

Benefits accruable to Generic Manufacturers

Market Exclusivity

The statute provides an incentive of "180 days (6 months) of Market Exclusivity"²⁸ to the "first" generic applicant who challenges a listed patent by filing a Paragraph - IV certification²⁹ and thereby upon the courts finding, that the innovator's patent is invalid or not infringed. During this period of 180 days, a huge profit is earned by the generics as they are the sole dealers or exclusive market holders of the drug.

For example, Ranbaxy, a pharmaceutical major, won the 180 day market exclusivity for "Simvastatin", an 80 mg, anti-cholesterol drug, in June, 2006. This exclusivity period gave the company a share of more than 55 percent in that market. It also earned about \$60 million during the same period.³⁰ Similarly, Dr Reddy's Laboratories' 'Fluxotene', a 40mg generic version of Eli Lilly's blockbuster drug 'Prozac', made \$70 million during the exclusivity period.³¹

26. 21 U.S.C. § 355(c) (3) (B).

27. 21 U.S.C. § 355(b) (2) (A) (iv).

28. In certain circumstances, the first applicant whose "Abbreviated New Drug Application (ANDA)" contains a Para - IV certification is protected from competition from subsequent generic versions of the same drug product for 180 days from either the date the first applicant's drug product is first commercially marketed or the date of a final court decision holding the patent that is the subject of the Para - IV certification invalid, unenforceable, or not infringed. This marketing protection is commonly known as "180-day exclusivity". http://www.fda.gov/cder/about/smallbiz/FR_generic_exclusivity.htm.

29. 21 U.S.C. 355 (j) (5) (B) (iv).

30. R. Rao, *Para - IV filing - The fight Continues*, MODERN PHARMACEUTICALS, August - September 2007. http://www.law.ou.edu/faculty/facfiles/Modern_Inervirew_2.pdf.

31. *You may have to pay more for Patented Drugs*, Jan. 10, 2005, <http://www.netdr.com/healthnews/patented-drugs.htm>.

Collusive Agreements

Sometimes, the innovator and the generic manufacturer enter into an agreement wherein the generic drug manufacturer is asked to refrain from entering the market on payment of a lump-sum amount by the innovator company. This practice prevents the entry of the other generic drug manufacturers from entering the market with a generic form of drug.

An illustration of such agreements can be found in the agreement entered into between Abbott Laboratories and Geneva Pharmaceuticals³² wherein Abbott marketed a pioneer brand-name anti-hypertension drug named “Hytrin” and Geneva Pharmaceuticals obtained approval for launching a generic version of “Hytrin”.³³ Hytrin, which is manufactured and marketed by Abbott, is the pioneer brand name drug in the United States containing terazosin HCL. Hytrin was introduced in 1987. It was the only terazosin HCL product sold in the United States until Geneva introduced such a product on or around August 13, 1999.³⁴ Abbott expected Geneva Pharmaceuticals to earn between \$1 million and \$1.5 million a month from the sale of that generic version³⁵ and to deter that generic version to enter the market, Abbott entered into an agreement with Geneva Pharmaceuticals. In the agreement, Abbott agreed to pay Geneva \$4.5 million per month³⁶ for not making and selling its competing generic version. This amount was very much less than what Abbott would stand to lose from the generic competition had Geneva’s generic version was launched, but, more than Geneva would make from the sale of its generic version.

So, such an agreement favored both the parties discarding the interest of the patients who would be compelled to purchase the original branded drug until the generic version was launched.³⁷

In another instance Schering – Plough a pharmaceutical giant, owned the patents for drugs named “K-Dur 20” and “K-Dur 10”³⁸ whose term was to expire on September 5, 2006. These drugs were used to treat patients with low potassium or hypokalemia. In August 1995, under procedures established

32. In re: Abbott Lab. & Geneva Pharmaceuticals, C - 3945, 2000 FTC <http://www.ftc.gov/os/2000/05/c3945complaint.htm>.

33. *Ibid.* Para. 24.

34. *Ibid.* Para. 11.

35. *Ibid.* Para. 25.

36. That is less than ten percent of what Abbott earns from sales of “Hytrin” per month. Total U.S. sales of Abbott’s terazosin HCL amount to approximately \$540 million per year. *Ibid.* Para. 10.

37. For more details see In re Abbott Lab. & Geneva Pharmaceuticals, C-3945, 2000 FTC, <http://www.ftc.gov/os/2000/05/c3945complaint.htm>.

38. The number in the product names refers to dosage strengths: the “20” tablets contain twice as much potassium as the “10” tablets. In the Matter of Schering-Plough Corporation, et al. Docket No. 9297, Leary, Commissioner, “Opinion of the Commission”, <http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf>.

by the Hatch-Waxman Act, Upsher-Smith, a generic manufacturer, filed an ANDA with the FDA to market “Klor Con M20”, a generic version of Schering’s “K-Dur 20”³⁹ with a Paragraph - IV certification in which Upsher certified that Schering’s patent was either invalid or not infringed by the Upsher’s generic version.⁴⁰ It received 180 days of “Market Exclusivity” to market its generic version; the period of which was to begin when the generic drug entered the market. Upsher subsequently notified Schering of this application and certification, as required by the Act.⁴¹ Schering then sued Upsher for patent infringement in the United States District Court for the District of New Jersey on December 15, 1995.⁴² Under Hatch - Waxman, this lawsuit triggered an automatic waiting period of up to 30 months (2.5 years approximately) for final FDA approval of Upsher’s product.

On June 17, 1997, on the eve of trial, Schering and Upsher settled their patent litigation by entering into a settlement agreement.⁴³ The automatic 30-month stay was still in effect, but was about to expire in a year, at the latest. In this settlement agreement, Schering-Plough also unlike Abbott, agreed to pay Upsher-Smith sixty million dollars and in return, Upsher-Smith agreed to wait almost four years (three years and three months from the agreement plus 180 days of exclusivity that will begin once Upsher-Smith begins the marketing.) before marketing its generic drug.⁴⁴

In light of the favour to the various pharmaceutical companies, this agreement can be of utmost importance but the real loss, as we can infer from the above mentioned examples, is faced by the low income patient groups because of such settlements, since they can never afford the price of the branded drug.

MEASURES THAT MAY BE ADOPTED BY INNOVATOR COMPANIES

Filing of Infringement Suit by the Innovator Company

In order to prevent frivolous Paragraph - IV certifications, the U.S. Congress made the “mere filing of the certification itself an act of infringement”

39. K-Dur 20 is used to treat patients who suffer from insufficient levels of potassium, a condition that can lead to serious cardiac problems. <http://www.ftc.gov/os/2002/02/ahpanalysis.htm>.

40. In the Matter of Schering-Plough Corporation, et al., Docket No. 9297, Leary, Commissioner, “Opinion of the Commission”, 3. <http://www.ftc.gov/os/adjpro/d9297/031218commissionop-inion.pdf>.

41. 21 U.S.C. § 355(j).

42. In the Matter of Schering-Plough Corporation, et al. Docket No. 9297, Leary, Commissioner, “Opinion of the Commission”, 4. <http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf>.

43. *Ibid.*

44. *Ibid.*

that gives the brand company the right to sue the generic company.

When the potential generic manufacturers files Paragraph - IV certification, the original patent holder is granted a period of 45 days from the day of notice to sue the generic manufacturer for infringing its patent. As soon as the infringement suit is filed by the innovator company, the statute provides that an automatic stay runs against that generic company for a period of 30 months during which the innovator company continues to have the “Exclusive Marketing Rights” (EMR)⁴⁵ to sell the drug even if the patent is proved to be invalid later. The innovator company continues to sell the drug at a higher price for a period of 30 months or until the Court decides the patent as invalid. Thus, the patients are deprived of the cheaper version of the drug for such further period and during this period the innovator company makes a huge profit out of the drug being the sole and exclusive dealer of the drug.

Evergreening

The innovators also resort to the practice of “Evergreening”⁴⁶ the patented drug by incorporating minor changes in the drug so as to keep the generics off the market by combining two different drugs sold separately into a single one as another strategy to thwart the generic competition⁴⁷. A glaring example of the successful use of evergreening strategies to obtain extended protection is GlaxoSmithKline’s version of the anti-depressant, “Paroxetine”, where the ‘base’ patent expired in the late 1990s’, but ancillary patents covering new forms, tablets, uses and processes will not expire until between 2006 and 2018.⁴⁸

Authorized Generics (AG)

Another way to prevent the entry of the generics in the market is through “Authorized Generics”. When the patent on the drug of the innovator is about to expire, the innovator company grants to any major generic

45. The term EMR means the Exclusive Marketing Rights to sell or distribute the article or substance covered in a patent or patent application in the country. The purpose of EMR’s is to ensure that the innovator can market free copies of the patented product. George Kutty, *India Patents - Exclusive Marketing Rights (EMR)*, [http://ezinearticles.com/?India-Patents-Exclusive-Marketing-Rights-\(EMR\)&id=79426](http://ezinearticles.com/?India-Patents-Exclusive-Marketing-Rights-(EMR)&id=79426).

46. “Evergreening” is a method by which technology producers keep their products updated, with the intent of maintaining patent protection for longer periods of time than would normally be permissible under the law, <http://en.wikipedia.org/wiki/Evergreening>.

47. Claritin D-24, a combination of decongestant and antihistamine in a once-daily dosage form, launched by Schering-Plough is an example of combination medicine. http://quamut.com/quamut/antihistaminedecongestant_combination.

48. M. Hutchins, *Using Interlocking Additional Early Stage Patents to Improve and Extend Patent Protection*, 3 INTERNATIONAL JOURNAL OF MEDICAL MARKETING 212, 215 (2003).

company the right to market a generic version of its drug before any of its competitors launch a generic version of that drug.

“Authorized Version” of the drug may be marketed by the innovator company itself or through its subsidiary, or by another company which has obtained a license from the innovator company on the product for marketing, in return for royalties.⁴⁹

A classic example can be taken of the pharmaceutical giant “Pfizer” who licensed its patented product to one of its own “Greenstone” subsidiary when it released a generic “Gabapentin” (Neurontin).⁵⁰ Similarly, “Novartis” has “Sandoz” as its subsidiary. These companies are launching their own Authorized Generic Drug Versions.⁵¹

The Authorized Generic Drug is sold at a lower cost as compared to the original branded drug and as an alternative to the branded product. For instance, Dr. Reddy’s was appointed as the Authorized Generic Company to launch the generic version of Merck’s cholesterol lowering drug, “Zocor” (Simvastatin) and “Proscar” (Finasteride).⁵²

Due to the Authorized Generic manufacturers, the drugs are still sold at higher prices and remain out of reach of the economically disadvantaged.

MEASURES THAT MAY BE ADOPTED BY GENERIC MANUFACTURERS

De-risking Option

Now, when the other generic companies were faced with the prospect of heavy losses because of the settlements between the innovator of the drug and any particular generic manufacturer, they also began to devise methods in order to safeguard their individual interests.

So, in order to de-risk their businesses, major generic manufacturers like Dr. Reddy’s entered into partnerships with ICICI and Citigroup Venture funds, whereby it was agreed that ICICI and Citigroup Venture funds will

49. Narinder Banait, *Authorized Generics: Antitrust Issues and the Hatch-Waxman Act*, http://www.fenwick.com/docstore/Publications/IP/Authorized_Generics.pdf.

50. Peter Wittner, *Authorized Generics - What are they?*, May 2006, http://www.genericsweb.com/index.php?object_id=380.

51. R. Unnikrishnan and K. Kabta, *Indian Generic Companies may tread Ranbaxy Path*, Jun. 19, 2008, http://economictimes.indiatimes.com/News/News_By_Industry/Healthcare__Biotech/Pharmaceuticals/Indian_generic_companies_may_tread_Ranbaxy_path/articleshow/3143221.cms.

52. Rakesh Rao, *Para - IV filing - The fight Continues*, Modern Pharmaceuticals, Aug. – Sept. 2007, http://www.law.ou.edu/faculty/facfiles/Modern_Inervirew_2.pdf.

fund a part of the Research and Development and litigation costs incurred by Dr. Reddy's.⁵³ In a \$56 million deal, ICICI Ventures would fund the development, registration and legal costs related to the commercialization of most of the U.S. ANDA's filed in 2004-05 and 2005-06.⁵⁴

ICICI Ventures would in turn receive a royalty on sales over a period of five years as and when Dr Reddy's would launch any of its generic versions of the drugs.⁵⁵ Ranbaxy too, while looking at other markets, is taken up by the Japanese Pharmaceutical major Daiichi Sankyo.⁵⁶

Some Perils of Paragraph – IV Filing

Paragraph - IV filings are not everyone's cup of tea. The companies resorting to a Paragraph - IV filing must have the financial muscle and ability to make the drug and face the onslaught of litigation.

In spite of the interest in this field, Paragraph - IV filings are risky, due to high litigation expenses. There is also the uncertainty of the legal outcome. However, on winning litigation, the costs are covered in approximately six months, which makes generic companies enthusiastic about such options. The huge cost involved in the patent challenge route is one of the major factors which have led to the decline in the number of challenge to the patent's validity.

According to experts, on an average, Paragraph - IV ANDA filing with the U.S. FDA costs about \$2 million including bio-studies preparation and ANDA draft. In addition, it costs, on an average, about \$15 - \$20 million to litigate a Drug Patent Case through appeal⁵⁷ and most companies lack the financial strength to bear the loss in case the company loses the litigation.

53. Ravi Krishnan and B.V. Mahalakshmi, *A Tale of Two Pharmacos*, THE FINANCIAL EXPRESS, Nov. 05, 2005, http://www.financialexpress.com/old/fe_archive_full_story.php?content_id=107658.

54. Sapna Dogra, *The Para - IV Charm continues*, Dec. 1 - 15, 2006. <http://www.expresspharmaonline.com/20060815/market11.shtml>.

55. *Supra* note. 53.

56. The takeover valued Ranbaxy, which will become a Daiichi subsidiary, at over \$8.4 billion, while making the Japanese company the world's fifteenth-largest drug maker from its current rating of 22. Daiichi will raise its Ranbaxy holding to a minimum of 50.1% through an open offer to shareholders at 737 rupees (US\$17) per share. Ranbaxy now has an opportunity to expand its presence in the global market while finding a much-larger partner to help shoulder its \$600 million in debt, picked up during a spending spree this decade. That will give Ranbaxy more freedom to consolidate its position in other sectors, such as financial services and healthcare. It will also be able to channel to India new high-quality drugs from Daiichi, noted for its innovation and excellent research base. Neeta Lal, *Ranbaxy Sale a Perfect Match*, ASIA TIMES, Jun. 19, 2008, http://www.atimes.com/atimes/South_Asia/JF19Df02.html.

57. *Increased ANDA Filing By Indian Generic Pharma*, http://www.lexorbis.com/Increased_ANDA_Filing_By_Indian_Generic_Pharma.htm.

Hence, unless generic companies have the financial strength to sop-up the losses, this may be a dicey escalation strategy.

IV. CONCLUSION

It can be stated that the worldwide benefits of ever better medicines have been tremendous. In recent decades, life expectancy has been increasing steadily in many parts of the world, often due to the availability of life – saving drugs. Consumers receive benefits from generic drugs because they are less expensive, cost effective and grant a better quality of life especially to those consumers with limited income.

The Hatch-Waxman Act has been an overall success, responsible for creating a generic drug industry.⁵⁸ Before the Hatch-Waxman Act, only 35% of branded drugs met generic competitors upon the expiration of the drug's patent, but now nearly every patented drug has a generic competitor upon expiration of the drug's patent.⁵⁹

Although intense price competition reduces the financial returns for brand-name drugs, at the same time, the patent period provides important protections, enabling the investment of U.S. drug companies in research and development which has grown rapidly with time – from \$26 billion in 2000 to about \$43 billion in 2006.⁶⁰

The Hatch Waxman Act has been successful in assisting more affordable generics into the market while at the same time maintaining the incentive for innovator companies to design and develop new life-saving drugs.

Since its enactment, however, several areas of abuse have delayed the entry of more affordable generic versions of drugs into the drug market. The 2003 Amendment to the Act⁶¹ has helped in removing some of the loopholes that existed, but has not proved to be completely successful.

58. A. Maureen Rouhi, *Beyond Hatch-Waxman: Legislative Action Seeks to Close Loopholes in U.S. Law that Delay Entry of Generics into the Market*, 80 CHEMICAL & ENGINEERING NEWS 38, 53 (2002).

59. *Ibid.*

60. Richard G. Frank, *Regulation of Follow on Biologics*, 357 NEW ENGLAND JOURNAL OF MEDICINE 841, 843 (2007).

61. Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 (j) (5) (B) (iv) (2000). This provision was later amended in 2003 in "Title XI of the Medicare Prescription Drug Improvement and Modernization Act" so that the 180-day exclusivity begins running only upon first commercial marketing subject to forfeiture events. 'Medicare Prescription Drug Improvement

In accordance with the purpose of the Hatch Waxman Act, it is vital to challenge settlements that act to keep generic drugs off the market. This is because the very purpose of enacting of the Hatch Waxman Act, i.e. “the access to medicines for the poor” and to strike a balance between the generics and the innovator’s drug still remains frustrated, as, both the innovator and the generic manufacturers are fighting to survive in the market while the loser remains the patient.

Broad Suggestions

There are two ways by which drugs may be accessible to the poor while protecting the rights of the innovator company. Firstly, the innovator company while investing a huge sum on the drug wants to recover the cost invested in the innovation and development of the drug. This cost is recovered from the sale of the drug and consumers are denied access to the affordable medicine for quite a long period. However, alternative mechanisms should be attuned to encourage Research and Development without relying on drug sales to fund drug development. Secondly, the brand payments must be considered per se invalid due to their anti-competitive nature and evergreening of patented drugs should not be allowed in any country.

With an increasing number of patent disputes breaking out across the globe, and increasing governmental concern that the current system is failing to deliver, it is in everyone’s interest that new mechanisms are found, at the earliest, as the pharmaceutical industry seeks to meet the needs of a highly competitive marketplace. It is likely that new legislative initiatives will be necessary to address concerns and confront challenges from both sides of the pharmaceutical industry.

The question still lingers, are we pleased with a system that is a problem solver to people with high incomes and which ignores the impact of inventions on the need of the general strata of society, the consuming public and the patients.