經濟部

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從美國藥品訴訟案例
看台灣學名藥廠發展之道

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摘要

生技醫藥發展主要是研發與專利之取得，國內醫藥產業發展至今，仍無突破性發展，且成效不彰，本研究就美國藥物相關法令及最近專利訴訟案例判判決結果之研析，探討目前相關法令之問題與醫藥產業之現況時，發現台灣目前醫藥生技產業之問題為；人才不足、研發能力不足、資金缺乏、臨床試驗經驗不足與環境不佳、國際行銷經驗欠缺、政府相關法令不完備、專利與授權管理經驗不足、市場太小等。在探討美國相關法令與案例時發現，美國政府在法令訂定時兼顧產業發展與大眾利益，對於專利訴訟案例判決結果，我們發現訴訟過程的冗長與費用，實非台灣中型醫藥業能負擔，而訴訟結果更是無法預期。過程中我們也訪談一些實務經驗豐富的律師及參訪績效非常好的製藥業，在對談當中發現，專利訴訟實在耗時耗錢，他們也建議盡量避免訴訟發生，因此專利管理與研發更為重要，台灣製藥業在發展學名藥時應該要有策略，不要發展一般性學名藥，要發展上等學名藥(Super Generic)，更要與國際大廠合作，拓展國際行銷業務。以下是我們的建議：找到利基產品，發展劑型藥；

(一) 強化研發能量與團隊；

(二) 面對訴訟要做好準備；

(三) 公司要做好專利管理工作；

(四) 政府要積極修法，營造適合發展的環境，如人體試驗等；

(五) 國內藥廠應該積極整併，發展自己的產品對抗競爭；

(六) 積極尋找合作對象，擴充通路，為產品尋找出路。

關鍵字：學名藥、專利藥、專利訴訟

Abstract

The key successful factors for the development of biotech and drug industry are the strength of R&D and derived patents. This research will discuss and research the reasons that Taiwan biotech and drug industry development is not good. On the basis of doing the research of related medical law and the recent patent litigation cases in USA as well as the problems of Taiwan drug industry interviewed with related people. We found some problems as the follows: shortage of qualified people, not good R&D capability, capital shortage, not good environment and experience, no global marketing experience, patent management shortage, and small market in Taiwan. They focus on the drug industry development and public interest while developing the related medical law when we did research the related law. We also found that there are much money and time will be required while patent litigation. Most of lawyers recommended that to avoid patent litigation is the best policy for Taiwanese companies. We had some comments and conclusions for Taiwan government and companies after doing this research as the follows:

1. To deveop niche products,
2. To enchance R&D team,
3. To prepare well to face patent ligitation,
4. To do well on patent management,
5. To have better law for Merge and Acquisition of Taiwan companies to develop niche product to face competition,
6. To seek good partners to extend channel system for products.

Keywords：Generic, Patent Drug, Patent Ligitation

壹、前言

一、緒論

根據生技中心市場報導指出：「台灣學名藥市場是國人投資藥廠賴以生存茁壯的重要領域，我國製藥產業因為規模不及跨國大藥廠，在新藥開發上的成效不彰，所以集中力量於開發專利到期的學名藥產品。透過參考原廠的數據資料，國內藥廠可以針對具有化學相等性的藥物，進行生物相等性(Bioequivalent-BE)與生物可行性(Bioavailability-BA)進行驗證，不需建立大量臨床試驗的資料，就可以取得國內藥政單位的核准上市。所需投入成本和風險都大幅降低，所以國內藥廠幾乎皆以學名藥作為主要的產品發展方向」。(生技中心，2007)

為爭奪有限的醫藥資源，國內藥品市場經常上演專利原廠與學名藥廠的各項競爭。這類競爭不只在台灣存在，從各國的醫藥政策到法庭攻防，將於第伍章「案例分析」討論，都可看到兩派角力，但是專利藥與學名藥其實是可以發揮相輔相成的功效。 代表專利藥市場利益的的原開發廠，多數集中在美、歐、日等三國廠商手中，由於具跨國公司規模，能運用龐大人力資源，向各國政府進行政策遊說。原開發廠對學名藥廠的指控，通常是以保護智慧財產權為主，其次是學名藥品質不佳，對病人權益將造成傷害，強調原開發廠的血統純正。因此多數跨國藥廠都會與學名藥市場劃清界限，突顯自己在創新研發過程中所做的努力。隨著各國醫藥財務支出愈來愈大，許多跨國原開發藥廠推出新藥過程時會出現瓶頸，為維持專利將過期暢銷藥品的市場利益，有些跨國原廠會私下與學名藥廠策略結盟，但願意公開看好學名藥市場的跨國大廠中，以諾華藥廠算是世界首例。從務實立場來看，諾華藥廠願意重新審視學名藥廠的市場潛力，與其他原開發廠相比，經營策略相當靈活，尤其當各國學名藥產業逐漸崛起時，能夠一邊保有專利藥品市場獨占性，又能搶攻專利過期的學名藥市場，就如台灣諾華總裁張振武所說：「十年之內，所有專利原廠，都會跟著諾華的策略進行調整。」由此可見學名藥的發展是未來各國政府必須正視的問題。

二、研究目的與研究背景

目前政府對學名藥藥品的管理與如何輔導及協助國內各藥廠面對各國際專利藥廠的侵權官司，似乎毫無積極作為，尤其對專利藥的管理無一套標準程序與合理法令，本研究係透過對美國法令的研究與美國學名藥相關訴訟案判例的研讀與分析，理解美國政府對學名藥廠的基本態度與各專利藥藥廠的提出侵權訴訟心態，整理出美國政府與專利藥藥廠對學名藥藥廠的管理與作為，並透過與美國學名藥廠 I 公司最高主管對談，了解其對各種法令的看法及其因應策略，加上與美國著名律師事務所律師對談之心得，提出對台灣政府與各學名藥藥廠提供建議，作為因應被告時的參考，也可做為政府對藥品管理法令政策訂定時之參考。

2006 年全球有約 230 億美元價值的藥品專利到期，2005 年至 2009 年間有累

計價值約 600 億美元的藥品專利到期，這些藥品中年銷售額超過 10 億美元的有 20 多種。這些藥物市場巨大，用藥人數長期保持穩定和上升，涵蓋了潰瘍病用藥、降壓藥、降脂藥、抗菌藥和抗腫瘤藥等多個領域。暢銷藥品專利到期，但具市場突破性的新藥後繼無力，對國際專利藥廠而言，將是個嚴峻的挑戰。

目前國內之製藥產業，仍以學名藥的產品為主。 爲如此龐大市場與攸關全民利益的學名藥管理更是重要，由於政府對這方面法令無明確的規範，藉由在美國研習期間與律師的訪談及參觀學名藥廠時與高階主管對談的機會，研究與學名藥相關法令及訴訟判例，試圖找出有利法規訂定之建議與對台灣藥廠發展學名藥的策略。

三、研究方法與研究流程

本研究係利用在美研習之便，參訪律師事務所及藥廠，實際收集到美國最新的法令與案例，就近研讀案例與訪談相關人士對談；再綜合分析後，提出可行建議供台灣藥廠與政府參考。

(一) 研究方法

如

圖 1 所示，先就台灣及美國與學名藥相關文獻、相關訴訟案判例、與法令收集後，詳細研讀與比較分析，並透過與專業律師訪談及學名藥廠 IMPAX 公司的高階主管對談，來印證美國大專利藥廠的心態及美國政府的法令對台灣學名藥廠的影響。

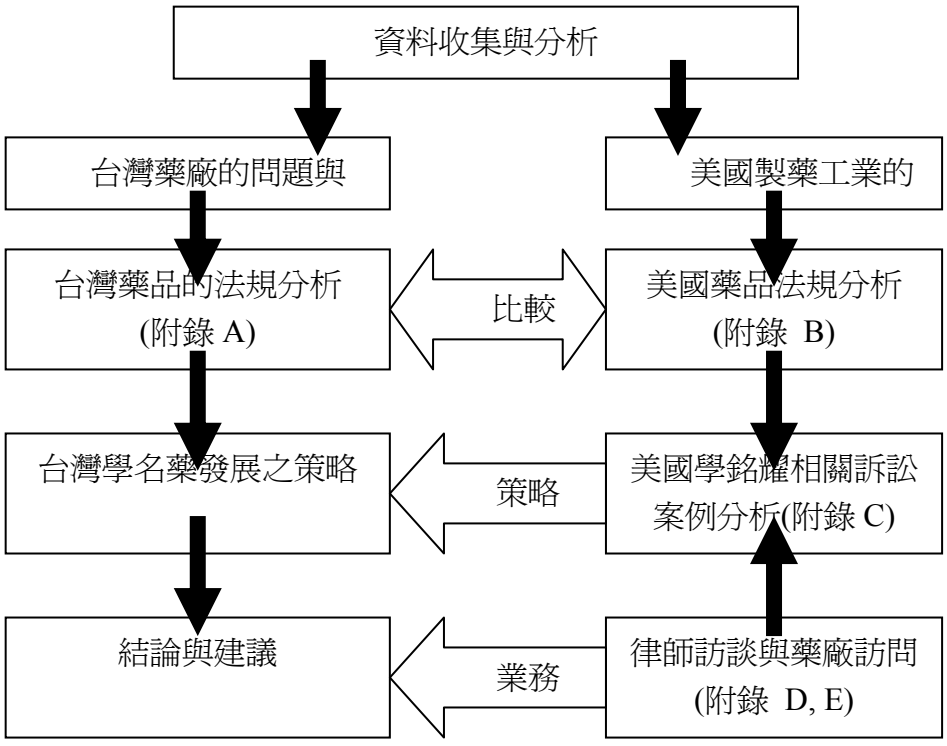

圖 1. 研究方法

(二) 研究流程

圖 2 是本論文的研究流程，五位學員經密切討論後，訂出研究主題並與指導教授進行研討，經其指導確立主題後，收集相關研究方法並根據小組在美國的資源決定研究方法，隨即進行資料收集彙整分析，並作專業訪談後整理，再根據分析結果撰寫論文，並多次請指導教授作指導。

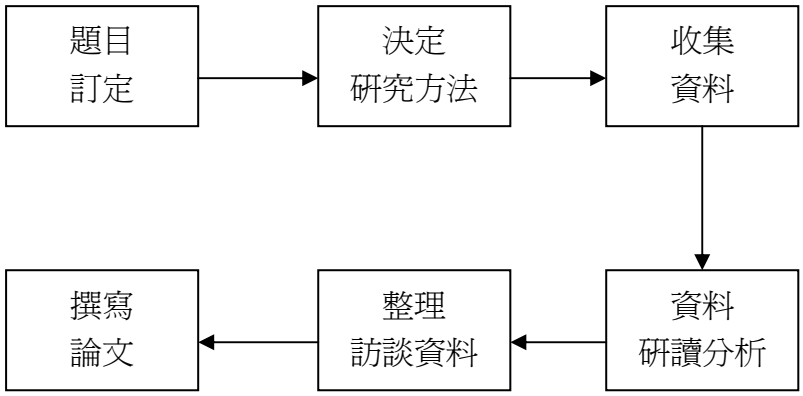

圖 2. 研究流程圖

貳、台灣藥業目前的問題與挑戰

一、緒論

藥品依專利過期與否，分為原廠藥(或稱為專利藥)和學名藥。原廠藥是指原開發廠新藥，通常會申請專利保護，確保上市後有一段時間可以市場獨占，藉以回收投資成本並獲利。學名藥（Generic Drugs）是原廠藥的專利權過期後，由其他合格藥廠依原廠藥申請專利時所公開的資訊，產製相同化學成分藥品，價格比原廠藥便宜許多。唯生產的廠商多，價格競爭激烈，利潤較低，品質也參差不齊。新原廠藥開發成本極高，原開發廠必須將所有研發過程中失敗與成功的費用納入成本，通常會申請專利保護，確保上市後有一段時間可以市場獨占。

從研究目的與背景中得知學名藥的成長非常快速，其主要原因為：(生技中心，2007)

- ＊ 醫療保險以降低醫療成本。
- ＊ 暢銷藥品專利到期。
- ＊ 人口老化。
- ＊ 法規的支持。
- ＊ 處方藥轉為非處方藥。

台灣藥廠因為規模小，資本又不如歐美大廠雄厚，因此在研發與國際行銷上無法有成效，為了生存，只有以近利策略來求生存。以下就目前台灣藥廠的相關問題作一概括性探討。

二、台灣藥業目前的問題與挑戰

目前政府雖然大力推動生技產業，但是到目前為止，績效不彰，詳細研究後發覺問題不少，而且面臨很大的挑戰，將一一分析如下：

(一)目前所面臨的挑戰

歐美大廠紛紛投入學名藥與積極進攻台灣藥品市場將是台灣藥廠非常嚴酷的挑戰，除了面臨競爭外，更要面對授權金的負擔，以下是目前最大的挑戰：

1. 印度及中國製藥產業的興起

中國被視為剛興起的明日之星，主要歸功於該國快速成長與景氣看好的產業活動。中國有 3,700 家以上符合 GMP 規範的製藥廠，部分跨國藥廠如 Lilly、Pfizer 與 Organon 等都已經將部分的研發活動移到中國大陸，Novartis 則是在上海成立新的研發中心，開始營運，至於已在中國佈局完善商業活動的 GlaxoSmithKline 亦考慮跟進。許多跨國藥廠都已經在中國擁有生產與銷售據點，而中國大陸之所以比印度更受人青睞的優勢在於其

生產製造成本相當低，市場大。近年來，印度學名藥廠持續利用併購策略來擴展其規模及地域範疇，並成功打入歐美等先進國家市場，印度藥廠在學名藥地位的的迅速壯大及旺盛的侵略企圖心已受到各界的關注。(工研院智網, 2007)

2. 偽藥仍困擾全球製藥產業

偽藥仍持續干擾製藥產業銷售，由於交易管道愈來愈多樣化、全球化以及網際網路等，使偽藥的交易愈來愈猖獗，且偽藥市場目前已經擴及到許多藥物，包括禽流感、一般抗生素、抗癌藥物及其他維生藥物等。雖然各界均認同必須迫切採取行動，但卻不知該由誰採取行動。歐洲政務委員會（Council of Europe，CoE）認為必須召集各國達成公約以打擊偽藥與製藥罪犯，而 CoE 為最適當的成立機構。但事實上，WHO 已經在執行此項工作，其所推動的「國際反偽藥工作小組」(International Medical Products AnticounterfeitingTaskforce，IMPACT）已經包含了 191 個國家及其產業與所有人。最後不論是誰將主導此項行動，所有相關者包括產業、海關、與法規管理單位等，都必須緊密合作以有效對抗此一危險的交易。反觀國內藥廠面對國內健保藥品給付價格持續刪減影響營收及獲利，也紛紛採取不同的因應對策。

台灣製藥業大廠，永信藥品除積極研發新藥外，近來更以 SAP 連接各廠，以達到資源共享效益，該公司預計 96 年底前台美將可開始資源共享，以使資源有效利用，97 年後系統將逐步整合至中國和馬來西亞廠。永信國內市占率約 3.4%，以往通路多為藥房與診所，近年大醫院比重才緩步上升。生達近年健保用藥佔其人用藥品的比例雖然逐漸下滑，但目前仍達 67%，未來將以拓展海外藥品市場與國內健康食品市場因應。其中生達於東南亞、中南美等新興國家將持續申請新的藥證，今年外銷比重估計將再小幅成長至 18%。

上市櫃生技股製造西藥原料藥的公司，多以外銷為主，但也會推出新的原料藥，例如生泰推呼吸道原料藥新產品、胃潰瘍原料新產品等。永日則以消炎陣痛原料藥為主，並生產崩散劑原料添加於藥丸，原料新藥目前沒推出，卻打算開發崩散劑醫藥以外的新用途。因此，目前外銷已成了國內藥廠一致的未來發展目標，惟全球醫藥產業已邁入全球化、大者恆大、產品生命周期縮短及利潤下滑的競爭激烈環境，對屬於中小型企業規模的台灣藥業，在產業結構、藥物開發及國際市場擴展，或應朝向企業整合、合作及團隊作戰的模式，共創雙贏的局面。

3. 學名藥廠市場成長但廠商競爭激烈

由於許多暢銷藥的專利於近年內到期，全球學名藥成長超過專利藥，估計其成長率在 18%至 19%間，全球的許多非專利藥廠已經磨刀霍霍，

開始盯上這些將過期的專利藥的仿製，原開發藥廠與學名藥廠間為爭奪學名藥市場而卯足勁。學名藥廠間的競爭也呈現白熱化，目前美國學名藥廠面對印度學名藥廠的低價競爭，加上原開發藥廠以上市所謂的「授權學名藥」（authorized generics）進入學名藥市場，壓縮了學名藥廠商的獲利空間，學名藥廠在經營上已面臨極大的威脅及艱辛，故以聯盟、併購及朝向利基型的新藥開發方向發展來搶攻市場。

4. 個人化醫療及利基產品開發將成趨勢

基因解碼的完成，對於基因標的及藥物作用標的的篩選有很大的助益，有別於過去用藥講究一體適用的藥學原則，未來的藥物開發的走向將針對特殊的族群而設計，在暢銷藥品（blockbuster）之產品線日益萎縮的情況下，利基產品（Niche buster）將成為明日之星。但是台灣藥廠面臨此種變化，如何利用此一利基，將是資金不大與研發能力不足的台灣藥廠一大挑戰。

(二)台灣藥廠所面臨的問題

生技製藥產業是一種重研發且資金需雄厚的產業，對高科技人才需求非常殷切，經過收集資料(含工研院與生技中心資料)分析整理後，發現目前台灣製藥產業的問題如下：

1. 人才不足

台灣製藥公司長期對於人才培養位加以重視，因此在國際行銷、專利管理、通路開發與管理、新藥研發等重要人才嚴重不足。

2. 研發能力不足

由於長期人力不足與未充分與國際接軌，對於新藥研發及人體試驗方面的技術與經驗不足，因此新藥出現機率較少，加上企業不願意花費經驗，導致研發技術無法落實生根。

3. 資金缺乏

由於過去台灣藥廠大部分屬於家族企業，作法過於保守，無法擴充與注入外部資金，屬於中小型企業，當要研發新藥、與國際藥廠合作、與拓展國際市場時常發生資金不足現象，所幸已經有一些公司上市櫃，對於資金募集有一定的幫助。

4. 臨床試驗經驗不足與環境不佳

因為政府過去對新藥的臨床試驗的相關法令不完備，導致製藥業對臨床試驗做的較少，因此經驗累積不足，加上願意參加試驗的人與條件不足，造成環境不佳。

5. 國際行銷經驗欠缺

因為台灣製藥業大都屬中小企業，又未有新藥開發，而所製造的藥較難通過FDA認證，也無自己品牌，無法於國際銷售，因此對國際行銷作為缺乏。加上國際行銷與國際通路的建立需有品牌與資金支持，台灣藥廠更加感到吃力。因為單靠台灣市場無法滿足業界需求，因此必須走到國際市場。

6. 政府相關法令不完備

過去政府對於醫藥產業之發展無大力扶持，加上業者大都屬於家族企業，因此對相關法令的準備與修訂往往趕不上國際腳步，由於不完備的法令，致使業者與國際大廠合作與國際大廠來台灣投資意願不足。

7. 專利與授權管理經驗不足

由於過去對人才培養的不夠重視，無法培養與國際接軌的人才，對於與國際大廠的專利授權與管理經驗明顯不足，因此此時只能借重國內外相關的專利與授權管理專業公司。

8. 市場太小

台灣雖然有健保醫葯市場支持，但是國際大廠的分食，國內藥廠所分食大餅已經無法滿足其發展，為支持其發展，對於開發中國家與未開發國家的市場，不得不大力進行佈建通路。

三、結語

生技製藥產業是高風險產業，需求資金與高級人才非常高，台灣生技與製藥產業一般規模較小，通常資金短缺與人才嚴重不足，在發展過程中往往碰到許多問題，尤其在通路與研發上更無法與國際大廠競爭，因此在此種惡劣環境下如何發展，更是業界與政府應該正視的問題，在下列各章節中將就美國目前的現況與其發展，並透過實地訪問藥廠及相關法令研析，試圖找出台灣藥廠發展的策略。

叁、美國學名藥與專利藥產業的現況

美國藥品在台灣佔的比例非常高，可以由以下的介紹了解，因此台灣政府與業界在發展生技醫藥產業時，對美國製藥產業及相關藥品的產業資訊不可不有詳細的了解，因此下列各節將就美國目前學名藥與專利藥產業現況作一分析，作為政府與產業界的參考。

一、美國學名藥與專利藥產業發展現況

眾所週知，在美國購買處方藥品可是相當昂貴的，世界各國人民對國際大藥廠所費不貲的藥價苦不堪言，甚至於起反感。學名藥既廉價藥效也相當，因此造就了學名藥品市場的需求市場，其市場競爭力往往可囊括原本專利藥品的七成以上。美國無論是在學名藥市場規模、營業額、人均消耗量或是人均藥物支出，都是全球最大的區域市場。美國也是全球公認學名藥產業的龍頭和最大市場，如圖 3 所示，依據美國學名藥協會(Generic Pharmaceutical Association, 以下簡稱 US GPha)在 2006 年公佈的資料顯示，2005 年美國處方藥藥品市場中已約有 56%為學名藥產品。(生技中心, 2007)

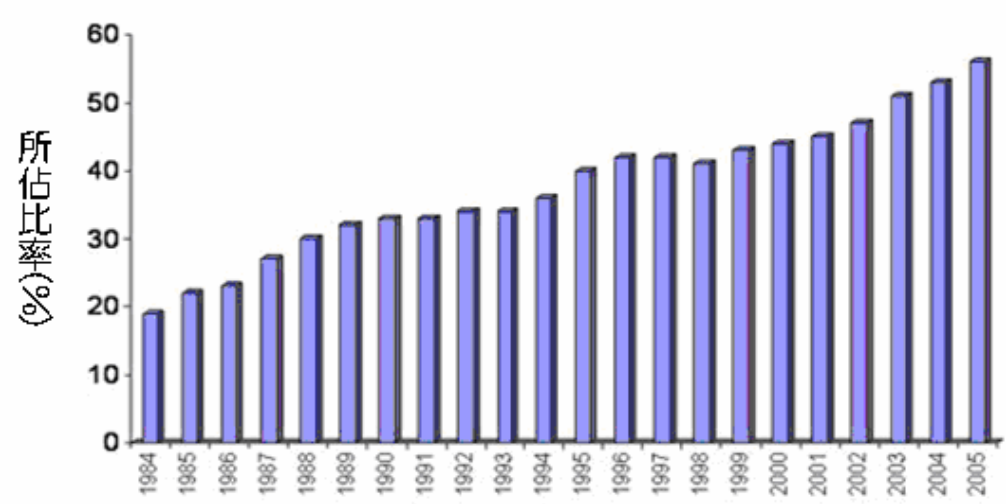

圖 3. 2005 美國處方藥籤市場的學名藥使用比率(資料來源：US GPha；生技中心 ITIS 計畫整理)

另外根據依據美國 GPha 估計，美國醫療保險以商業保險為主，因自由市場機制，學名藥與原開發廠之間藥價差距大。未來在消費者主動選擇低價學名藥、政府降低醫療成本的壓力和專利即將過期的暢銷藥等主要因素促進下，預估美國學名藥市場規模會逐年增加，在 2009 年時美國的學名藥品市場規模將達到約 440 億美元。如下列表 1：美國學名藥產業側寫，說明美國目前學名藥的現況。

另外依據美國 GPha 在 2006 年公告的統計資料顯示，未來從 2006 年開始，

美國藥品市場上有許多排名在 FDA 處方藥簽的前 50 名用藥已經/將要專利到期，依照往例，將有學名藥產品上市，將會讓美國學名藥市場結構更進一步改變，表 2 是生技中心於 2007 年所整理的資訊，列表即將到期或已經到期的專利藥。

但是美國政府為了大眾利益及展望未來美國學名藥市場在開放廣告後消費者自行選擇外，在美國政府降低保健支出的動力下，將會有更多的醫生及保險公司採用學名藥，未來市場成長可期，圖 4 顯示的是學名藥到 2009 年的成長趨勢。

表 1. 美國學名藥產業側寫(資料來源 US GPA；生技中心 ITIS 計畫整理)

項目	產業重點
產業特色	□2003~2004年美國學名藥市場規模成長了10% □2005年美國品牌藥廠銷售額2295億美元，美國學名藥廠銷售額223億美元，約佔9.7%。 □美國前五大處方藥廠，有4家是學名藥廠(Novartis (Sandoz), Teva, Mylan, Watson) □FDA 的橘皮書中名列的 11,167 項藥品中有 8,400 項是有學名藥相對應(generic counterpart)
學名處方藥	□2005年美國藥品市場中約有56%的處方藥為學名藥產品 □2005年學名藥產品被使用於超過10億處方藥籤 □前十大被處方藥籤使用的學名藥，是 Hydrocodone/APAP(麻醉止痛), Amoxicillin, Lisinopril, Hydrochlorothiazide, Atenolol(降血壓藥), Furosemide Oral(利尿劑), Alprazolam, Albuterol Aerosol, Levothyroxine, Metformin.
學名藥節省的醫療成本	□2004年，美國每一份學名處方藥平均價格是28.71 美元，每一份品牌藥平均藥格是95.54 美元，亦即減少了69.9%的醫療成本。 □依據1998年美國國會預算辦公室(Congressional Budget Office)的統計資料，顯示每一年學名藥替美國消費者節省了80~100 億美元 □學名藥約佔了美國處方藥市場的 56%，但是僅佔了不到 13%的處方藥銷售價值，亦即學名藥售價平均比品牌藥便宜是 30~80%
市場趨勢	□2005年美國學名藥約248億美元，2006年預期成長13% □2006年預估有價值220億美元的暢銷藥品專利到期 □2007年預估有270億美元的暢銷藥品專利到期 □2008年預估有290億美元的暢銷藥品專利到期

表 2. 未來 3 年美國專利到期的處方藥品 (資料來源：Frost & Sullivan, Express Scripts；生技中心 ITIS 計畫整理)

品牌名	學名藥	專利擁有廠商	專利到期
Proscar	finasteride	Merck	2006年6月
Zocor	Simvastatin	Merck	2006年6月
Provigil	Modafinil	Cephalon	2006年6月
Doxil	doxorubicin liposome injection	Ortho Biotech	2006年6月
Zoloft	sertraline	Pfizer	2006年6月
Maxaquin	lomefloxacin	Pfizer	2006年8月
Wellbutrin XL	Bupropion extended release	GlaxoSmithKline	2006年8月
Zofran	ondansetron	GlaxoSmithKline	2006年12月
Lotrel	Amlodipi and benazepril	Novartis	2007年1月
Norvasc	Amlodipine	Pfizer	2007年1月
Actiq	fentanyl transmucosal	Cephalon	2007年2月
Aceon	perindopril	Solvay	2007年2月
Alocril	nedocromil	Allergan	2007年4月
Imitrex	sumatriptan	GlaxoSmithKline	2007年6月
Geodon	ziprasidone	Pfizer	2007年9月
Coreg	carvedilol	GlaxoSmithKline	2007年9月
Meridia	sibutramine	Abbott	2007年12月
Mavik	trandolapril	Abbott	2007年12月
Tequin	gatifloxacin	GlaxoSmithKline	2007年12月
Zyrtec	cetirizine	Pfizer	2007年12月
Clarinex	desloratadine	Schering-Plough	2008年2月
Fosamax	alendronate	Merck	2008年2月
Camptosar	irinotecan	Pfizer	2008年2月
Effexor/XR	venlafaxine	Wyeth	2008年6月
Zymar	gatifloxacin	Allergan	2008年6月

Dovonex	calcipotriene	Bristol-Myers Squibb	2008年6月
Kytril	granisetron	Roche	2008年6月
Risperdal	risperidone	Janssen	2008年6月
Depakote	divalproex sodium	Abbott	2008年7月
Advair	fluticasone and salmeterol	GlaxoSmithKline	2008年8月
Serevent	salmeterol	GlaxoSmithKline	2008年8月
Casodex	bicalutamide	Bristol-Myers Squibb	2008年10月
Trusopt	dorzolamide	Merck	2008年10月
Zerit	stavudine	Bristol-Myers Squibb	2008年12月
Lamictal	lamotrigine	GlaxoSmithKline	2009年1月
Vexol	rimexolone	Alcon Labs	2009年1月
Avandia	rosiglitazone	GlaxoSmithKline	2009年2月
Topamax	topiramate	Johnson & Johnson	2009年3月
Glyset	miglitol	Pfizer	2009年7月
Acular	ketorolac tromethamine	Allergan	2009年11月
Xenical	orlistat	Roche	2009年12月
Valtrex	valacyclovir	GlaxoSmithKline	2009年12月
Avelox	moxifloxacin	Bayer	2009年12月

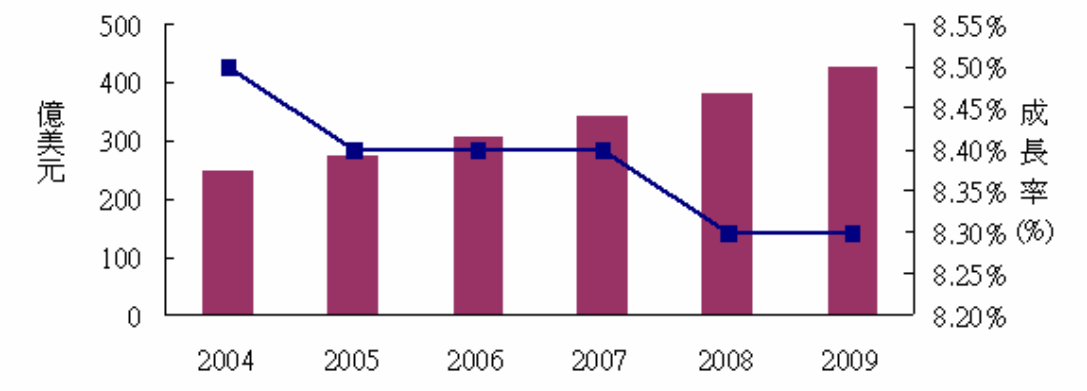

圖 4. 美國學名藥市場規模與趨勢預估(資料來源：Espicom；生技中心 ITIS 計畫整理)

二、台灣學名藥廠與美國專利藥廠關係分析

許多美國及國際大藥廠看中台灣健保七百五十億學名藥市場大餅，歐洲最大、全球第二大學名藥公司「山德士（SANDOZ）」正式進軍台灣，宣布以比原廠藥便宜一到二成價格，讓民眾享受和原廠同品質藥品，也節省健保藥費支出。

過去原廠藥是外商藥廠天下，學名藥多由本土藥廠產製，涇渭分明，山德士進軍台灣，本土藥廠首當其衝。台灣區製藥工業同業公會理事長黃柏熊表示，國產藥廠對自己的產品有信心，尤其是通過「生體可用率或生體相等性（BA／BE）實驗」的產品，品質也不遜原廠。「學名藥市場本來就很競爭！」黃柏熊表示，不怕外商來挑戰。山德士是外商諾華藥廠子公司，台灣諾華總裁張振武指出，全球老年人口及醫療需求增加，健保支出也居高不下，學名藥將是減少醫療費用支出的關鍵因素，目前全球學名藥市場高達七百億美元，估計未來十年有更多明星藥品專利過期，學名藥市場將逾千億美元；台灣健保藥費支出去年達一千一百億元，其中約七百五十億元用於學名藥。

目前國內許多大的藥廠通常是生產學名藥，或是代理國外藥廠的專利藥在台灣銷售，甚少有自行研發的新藥，台灣與美國藥廠之間形成共生關係，但是專利藥廠爲了保障自己利益，對台灣藥廠自行生產學名藥，還是會有所動作，如提告來迫使台灣藥廠面對，爲自己爭取時間來保障自己利益，台灣藥廠因為打不起國際官司，往往會主動與美國專利藥廠談判達成和解，雙方之間所達成協議，或許對雙方都有一定的利益，但對消費者未必有利，更對藥價黑洞沒有改善的助益。除了政府必須面對外，台灣藥廠如何與美國藥廠維持互利關係是必須深思的課題。

三、結語

從以上資料顯示，我們可以了解美國製藥大廠的專利藥過期或即將過期品項很多，加上美國政府為了大眾利益鼓勵學名藥上市，以降低民眾之利益，也從中

理解到各大藥廠也積極介入學名藥市場，因此未來學名藥市場將會是競爭激烈局面，台灣藥廠若僅介入學名藥廠的生產，將會很艱難，若能積極與美國或其他國際大廠策略聯盟，將會較有生存機會。

肆、台灣與美國學名藥法令比較

台灣藥廠的發展除了要自力更生，強化體質外，更應積極尋求與國際大廠合作，尤其與美國大廠的合作更是重要策略，因為美國市場是重要的消費市場，因此理解美國藥品相關法令是必要的工作，也可以藉由美國法令來檢視台灣相關法令，希望由政府營造適合台灣藥廠法展的法令，下列是分析台美雙方的學名藥法規。

一、台灣藥品管理法規現況分析

(一)、台灣藥事法規之探討分析

台灣醫藥主要法規為「藥事法」，其規範醫藥之申請、製造、販賣等活動，其與學名藥相關之法令無專章規範，其中只有第 40、40-1、40-2 三條文規範要務申請等要件，其中第 40 條「製造、輸入醫療器材，應向中央衛生主管機關申請查驗登記並繳納費用，經核准發給醫療器材許可證後，始得製造或輸入。前項輸入醫療器材，應由醫療器材許可證所有人或其授權者輸入。申請醫療器材查驗登記、許可證變更、移轉、展延登記、換發及補發，其申請條件、審查程序、核准基準及其他應遵行之事項，由中央衛生主管機
關定之。」，為基本之規範，而第 40-1 條「中央衛生主管機關為維護公益之目的，於必要時，得公開所持有及保管藥商申請製造或輸入藥物所檢附之藥物成分、仿單等相關資料。但對於藥商申請新藥查驗登記屬於營業秘密之資料，應保密之。前項得公開事項之範圍及方式，其辦法由中央衛生主管機關定之。」，及第 40-2 條「中央衛生主管機關於核發新藥許可證時，應公開申請人檢附之已揭露專利字號或案號。新成分新藥許可證自核發之日起五年內，其他藥商非經許可證所有人同意，不得引據其申請資料申請查驗登記。新成分新藥許可證核發之日起三年後，其他藥商得依本法及相關法規有關藥品查驗登記審查之規定提出同成分、同劑型、同劑量及同單位含量藥品之查驗登記申請，符合規定者，得於新成分新藥許可證核發屆滿五年之翌日起發給藥品許可證。新成分新藥在外國取得上市許可後三年內，必須向中央衛生主管機關申請查驗登記，始得準用第二項之規定。新藥專利權不及於藥商申請查驗登記前所進行之研究、教學或試驗。」，此一條文與學名藥較有相關，此點就與美國有極大不同，美國有專門法案來規範學名藥之發展，因此使學名藥發展更迅速，也兼顧大眾利益。

(二)、台灣相關學名藥訴訟案例分析

台灣有關學名藥之法律事實上並未定義的非常清楚，甚至沒有明列於適當法律位階之條文中。台灣之製藥產業 100%為學名藥廠，但相關重要法令卻只定義了新藥，此應無法符合台灣產業狀況。請參考相關法令規章。(附錄一)

最近的幾個判例值得大家深思，以下的報導就可以了解台灣對學名藥法律問題的見解的分歧；(摘錄自聯合新聞網)

「最近學名藥仿單之著作權侵權案件，日益增加，但各法院對於藥品仿單是

否應受著作權法保護，以及藥品查驗登記審查準則是否可以作為阻卻著作權侵害之事由，見解卻相當紛歧。台灣高等法院 94 年度智上字第 17 號民事判決及台灣高等法院台中分院 95 年度智上字第 9 號民事判決則分別於 2007 年 2 月 13 日及同年 1 月 14 日針對兩件上訴案於近日判決認定學名藥仿單不構成著作權侵權。

依據行政院衛生署發布施行之藥品查驗登記審查準則第 4 條第 2 款規定，與國內已核准之藥品具同成分、同劑型、同劑量、同療效之藥劑，稱為學名藥。由於該條款所稱之已核准之藥品，通常未曾取得專利或專利已過期，學名藥通常不會有專利侵權之問題。但實務上卻發生學名藥之仿單（即藥品之使用說明書）面臨著作權侵權之重大危機。

有關著作權方面之主要爭議，在於藥品仿單是否為著作權法所保護之著作、著作財產權人為何、以及學名藥之仿單是否構成著作權侵害。目前實務見解雖就藥品仿單是否為著作權法所保護之著作，尚有爭議，但有相當多法院採肯定見解。著作財產權人為何，則需個案認定。至於學名藥之仿單相同是否構成著作權侵害，法院見解較為紛歧。

台北地方法院 2005 年 3 月 31 日 93 年度智字第 81 號民事判決針對具體個案，除肯定藥品仿單乃著作權法所保護之著作外，並認為該案件之學名藥的仿單，未經授權使用已核准之藥品仿單，構成著作權侵害。該案件之學名藥的製造廠商，雖援引藥品查驗登記審查準則第 20 條第 3 款規定作為抗辯，主張依該條款規定，監視藥品之學名藥仿單，應依已核准之首家仿單核定方式記載，非監視藥品應依原廠仿單據實翻譯；因此，對於學名藥仿單之內容，受限於行政院衛生署之規定，並無另行創作之自由。不過，台北地方法院則認為藥品查驗登記審查準則僅為行政規範，並無法推翻著作權法規定之效力。

南投地方法院 2006 年 3 月 23 日 94 年度智字第 3 號民事判決針對相同學名藥之案情，則採取迥然不同之見解。南投地方法院則認為藥品查驗登記審查準則可以作為阻卻著作權侵害之事由。此外，在刑事案件部分，台北地方法院檢察署 2006 年 12 月 18 日 95 年度偵字第 25746 號不起訴處分書則以被告係依藥品查驗登記審查準則而制作仿單，欠缺主觀犯意，而為不起訴處分。

前述之兩件地方法院民事判決經上訴高等法院後，台灣高等法院 2007 年 2 月 13 日 94 年度智上字第 17 號民事判決及台灣高等法院台中分院 2007 年 1 月 14 日 95 年度智上字第 9 號民事判決則均認定學名藥仿單不構成著作權侵權，尤其台灣高等法院台中分院 95 年度智上字第 9 號民事判決更進一步否定藥品仿單為著作權法保護之著作。

兩件案件均上訴至最高法院，而最高法院之見解與判決結果，對於未來各級法院案件之審理，將產生相當大之影響。由以上的判例，足見台灣相關法令仍不夠健全，此一問題亦不利台灣學名藥之發展。

二、美國藥品法規現況分析

美國之藥品發展，在 1962 年之前，於美國申請藥品上市只需要證明其安全性即可，而學名藥的部份甚至只要利用文獻資料證明其安全性即可（不需實驗數據證實）；基於藥物安全以及有效性之考量，1962 年美國政府修法要求須同時證明藥品之安全性以及有效性才能獲得美國食品藥物管理局（Food and Drug Administration-FDA）之核准，但如此一來學名藥廠須花費大量的時間與金錢進行臨床試驗，導致法令實施後學名藥之數量急遽下滑，因此造成市場藥品價格高居不下；因此美國於 1984 年通過實行了藥品易價格競爭與專利期間回復法（Drug Price Competition and Patent Term Restoration Act），也就是大多人所謂的 Hatch-Waxman Act。(王怡云, 2007)本段主要敘述 Hatch-Waxman Act 即 CREATE ACT 法案的主要精神與重要條文，原文請參考附錄二。

(一) Hatch & Waxman Act

Hatch-Waxman Act 對於美國學名藥產業及國際學名藥業之發展的影響深遠，為非常重大之政策，依據 Hatch-Waxman Act 之精神修改了美國的聯邦食品藥品與化妝品法（Federal Food, Drug, and Cosmetic Act）以及專利法，因而使美國學名藥產業節節成長，由圖四的成長趨勢圖就可清楚。下列將就本法案的基本條文及精神說明如下：

1. Hatch-Waxman Act 法案精神與重要概念

(1)為使學名藥快速核准上市，簡化審查程序

美國政府與國會為顧及大眾利益與降低藥品價格，以立法手段鼓勵學名藥能快速進入市場，法案中明定，只要學名藥公司能夠證明其藥品與已通過上市的新藥品申請（New Drug Application, 簡稱 NDA），其學名藥具有與已通過上市的新藥品相同的成分、劑型、藥效以及生體相等性試驗（Bioequivalent, 簡稱 BE），FDA 即可通過該學名藥公司之學名藥申請或稱縮短型新藥申請（Abbreviated New Drug Application, 簡稱 ANDA），這樣就可以大大縮短專利藥逾期後學名藥快速進入市場的時間，藉以降低醫療藥品費用，節省大眾醫療費用支出。而其中生體相等性試驗（BE trial）的意義即為利用同成分、同劑型、同劑量之原開發廠藥品以及學名藥品給予同一位受試者服用，用以確認其於受試者體內之藥效相同。

爲使學名藥能及早上市，學名藥廠可於原開發廠之藥品專利尚未逾期前先申請 ANDA，乃由於藥品的上市除需進行相關之各式試驗外，仍須經過 FDA 之嚴格審查（一般平均需要超過 30 個月），因此 Hatch-Waxman

Act 允許學名藥廠於專利藥品專利有效期間將相關申請工作準備好，如此可於專利逾期的第一天即可上市供應給民眾使用。

(2)自動停止審查 30 個月（Automatic 30-month stay）

此依規定與精神是在保護專利藥廠，規定中明訂任何 ANDA 申請者在提出第四種證明後，ANDA 申請者必須同時通知 NDA 擁有者，而 NDA 擁有者須於 45 天內決定是否提出侵權訴訟，若 NDA 擁有者提出訴訟，FDA 將自動停止審查 30 個月直到符合下列條件才繼續審理該案件：

a. NDA 專利期滿。
b. 侵權訴訟之結果，法院判定 NDA 專利無效或是 ANDA 並未侵權。
c. 30 個月期滿。
d. 180 天市場獨賣權（180-day exclusivity right）：此一規定係在鼓勵學。

名藥廠申請第四種證明，以為鼓勵學名藥廠及保障專利擁有者之權利，其規定是明訂任何一家申請 ANDA 第四類成功上市，FDA 將會給予從第一天上市算起 180 天的獨賣期，也就是說 FDA 於 180 天期間將不會再通過任何一家 ANDA 申請。

(3)建立"橘皮書"（Orange Book）機制

雖然 Hatch-Waxman Act 讓學名藥廠可於專利逾期前先行申請 ANDA，但是仍須沒有專利侵權的行為發生，因此 Hatch-Waxman Act 規定，原專利藥廠於申請 NDA 時，必需提供所申請新藥之主成分、劑型、組成或應用等相關之專利資料給 FDA，當 NDA 被申請核准後，同時這些專利資料將會登陸於 FDA 的橘皮書中公開供大眾閱覽；因此學名藥廠在 ANDA 提出申請時，必須詳細比對橘皮書中公開之專利資料，向 FDA 提出相關證明，作為 FDA 核發藥證的準則或依據，其證明分以下四種：

a. 第一種證明（製藥界稱為 Paragraph I）：

即證明橘皮書中並未有與 ANDA 相關之專利，只要提出申請的必要文件以及 BE 試驗結果符合，FDA 即可核發藥證。

b. 第二種證明（製藥界稱為 Paragraph II）：

即證明 NDA 相關專利已經期滿無效，如第一種，只要提出申請的必要文件以及 BE 試驗結果符合，FDA 即可核發藥證。

c. 第三種證明（製藥界稱為 Paragraph III）：

即使橘皮書中之相關專利還有效，但學名藥廠申請 ANDA 承諾當相關專利逾期後才申請認證，所以 FDA 將於專利逾期後才會通過該 ANDA 藥證。

d. 第四種證明（製藥界稱為 Paragraph IV）：

為最複雜且最困難的部份，學名藥廠在提出 ANDA 申請時，必須提出證明專利藥廠在申請 NDA 時之相關專利是無效的，或者是提出證明，在 ANDA 申請時無專利侵權之虞。

(4) 專利條件回復（Patent term restoration）

政府爲鼓勵學名藥的上市，以降低大眾的負擔與保障大眾健康，和減輕政府財政支出，然由於新藥開發困難度高，爲保障原開發藥廠及鼓勵繼續開發新藥，FDA 也給予原開發廠對等之鼓勵機制。因此當 FDA 通過原開發藥廠之 NDA 後之 60 天內，原開發廠可向美國專利商標局（United States Patent and Trademark Office, USPTO）申請專利條件回復，用以彌補專利藥品用於臨床試驗所花費的時間以及向 FDA 申請審查時所花費之時間，但此專利條件回復之延長時間不得大於 5 年。

2. Hatch-Waxman Act 法案於 2003 年的修改重點

Hatch-Waxman Act 實施多年後，也發現諸多問題及不合理之處，因此布希政府於 2003 年修改 Hatch-Waxman Act，其主要修改要點與精神分述如后：

(1) 自動停止審查 30 個月（Automatic 30-month stay）僅限用 1 次：

原法令並未禁止原開發廠申請自動停止審查的次數，因此同一個 ANDA 申請案中原開發藥廠可利用相關的不同專利一直提出 30 個月停止審查權之申請，變相的阻止 FDA 審查；使得學名藥廠的學名藥無法上市與獲得藥証，因此新法令修改後，任何一個 ANDA 申請案僅允許一次因相關專利訴訟而中止審查。

(2) 學名藥廠在申請 ANDA 時選擇第四種證明(Paregraph IV)時，應通知 NDA 擁有者之期限：

新規定為學名藥廠申請 ANDA 時必須於 20 天內通知 NDA 擁有者。

(3) 學名藥廠在申請 ANDA 可提出宣示性判決(declaratory judgment)：

原法案中規定，若學名藥廠在申請 ANDA 時通知 NDA 擁有者，45 天內 NDA 擁有者若未提起侵權訴訟，學名藥廠即可獲得藥證核發，但是上市仍背負著侵權之風險；因此新規定為；若 NDA 擁有者於 45 天內未提起訴訟，學名藥廠 ANDA 的申請可於已提供 NDA 其申請相關秘密資料的前提下，申請宣示性判決動作(declaratory judgment action)以主動尋求法律上之確認。

(4) 學名藥廠提出 ANDA 申請，可在侵權訴訟中，可提起反訴訟 (counterclaim)：

因為新增訂 ANDA 申請者可要求 NDA 擁有者移除橘皮書(Orange Book)中未包含於通過認證藥物或認證藥物使用方法之專利，但不能提出損害賠償。

(5) 釐清 180 天市場獨賣權（180-day exclusivity right）：

原法令中因未明確規定，因此同一 ANDA 若有不同之專利，利用第四種證明(Paragraph IV)挑戰不同專利之所有 ANDA 申請者將共享 180 天市場獨賣權權；為釐清此點，新規定只對第一位提出第四種證明(Paragraph IV)之 ANDA 申請者能獲得此市場獨賣權。

(二) CREATE ACT 法案的精神與重點

Create Act 是一種對專利藥很有好處的法案，法案原文請參閱附錄二，但對學名藥的價值不多，本法案的重點是，藥廠可以長期與大學合作研究，並可以較便宜的取得發明的權利，而其允許 Create Act 法案的合作者取得範圍較窄的發明並快速的取得專利保護，且阻絕競爭。Integra 大大的降低研究工具專利的價值，被廣泛用在製藥工業，法律或許可以解決問題，但是競爭者或大學(研究工具專利的擁有者)不會放棄捍衛其價值的權利，來對抗製藥工業。本法案主要是鼓勵協同合作研發，透過本法案的通過，以專利相互共有與分享來鼓勵發明者、藥廠、學校、與合作個人確實合作，本法案的實施，使得合作各方都能互蒙其利，台灣可以利用此依精神來立法鼓勵，將有助提升台灣醫藥產業的研發與發展。

三、結語

從上述的研析，我們認為美國政府所制定的法令規章，對各類利益團體都有適度的照顧，更對大眾的利益給於關注與照顧，所以法令之制定與執行，較為完

備，但是維護學名藥與專利藥業者的法案，在立法與利益維護的角度上是互相衝突的，因此，台灣在思考可借鏡處時，也必須考量國內產業與市場在不同階段的需求。

伍、美國有關學名藥案例分析

台灣學名藥廠常會碰到原專利藥廠的侵權訴訟與不公平的競爭，除了必須了解美國藥品相關法令外，若能對最近的一些訴訟案例判決過程與結果了解，將有助於爾後可能面對的侵權訴訟，決定訴訟策略與防禦方式，因此本文將就最近的案例加以研讀分析，了解該案例對台灣之影響，加強面對訴訟的應變能力，以下就三案例加以敘述分析。

一、SCHERING-PLOUGH CORP. v. FTC 案對台灣學名藥廠發展之影響

(一) 訴訟標的

SCHERING-PLOUGH CORPORATION, UPSHER-SMITH LABORATORIES, INC., Petitioners, versus FEDERAL TRADE COMMISSION, Respondent: SCHERING-PLOUGH CORPORATION, UPSHER-SMITH LABORATORIES, INC 對 FTC 反托拉斯法案成立不服提起上訴

(二) 訴訟案背景資料及裁定結果概述

SCHERING-PLOUGH, UPSHER-SMITH LABORATORIES, INC 公司因為學名藥的進入市場問題，因為相互間的利益問題，採取相互和解方式來擴大市場，其中 Schering 控告 Plough 侵權後，以和解談判來解決爭端，後來更採取相互授權來擴大市場模式，又有 ESI 公司也加入學名藥市場，也是以和解手段來相互授權來解決雙方因學名藥侵權的問題，因此 FTC(Federal Trade Commission)以行政手段來控告兩家公司有壟斷市場嫌疑，認為合約不合法，違反 FTC 法案的 15U.S.C.§45 及 SHERMAN 法案的 15U.S.C. §1，而以行政法院判定 SCHERING/PLOUGH/ESI 三家公司違反反托拉斯法案 (antitrust)成立，行政法院提出許多案例來佐證此案的不合法性，如 issue." Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1303-04 (11th Cir. 2003) (citing NCAA v. Bd. of Regents Okla. Univ., 468 U.S. 85, 103, 104 S.Ct. 2948, 2962, 82 L.Ed.2d 70 (1984))的判.Schering 及 Plough 公司不服上訴，後來聯邦巡迴上訴法院裁定 FTA 的命令無效。判決結果如下：

在巡迴法庭建立案例，因為一個專利藥公司擁有專利卻付給其學名藥競爭對手錢而不算是違反反托拉斯法案。這必須強調專利之強度，我們的決論是希望 FTC 必須注意這一點來反應政策，對於各方訴訟費用，公眾的問題與過多的法院案件，及公私利益相互關聯有關，我們深怕並拒絕任何一項法律自動對專利擁有者以談判學名藥進入市場的日期、及其輔助性的交易來解決專利侵權的合約宣告

無效，此種結果不能將專利與反托拉斯法案混為一談。
因此法庭審查本上訴案，因此上訴法院撤銷FTC的決定及FTC必須終止其命令。

(三) 對台灣學名藥廠的影響與建議

雙方為各自利益與市場佔有，常透過和解來解決爭端，常常透過相互授權來增加雙方的利益，而罔顧大眾的利益，或利用 Hatch-Waxman 法案來爲自己爭取時間多賺一些錢，本案對學名藥廠來說並沒有特別的好處，乃因為三家公司都擁有一些專利，對專利較少的學名藥廠與研發能力較弱的台灣藥廠來說，我們認為若是碰到專利侵權官司時，應以和解來解決爭端，因為台灣藥廠對於侵權訴訟較無能力參與國際訴訟。

二、TEVA PHARAMACEUTICALS v. NOVARTIS PHARAMACEUTICALS 案對台灣學名藥廠發展之影響

(一) 訴訟標的

Novartis 在申請 Famvir® NDA(New Drug Application)藥證時，亦針對 Famvir®的相關特性，同時登錄 5 項專利在 FDA(Food and Drug Administration)的橘皮書(Orange Book)中：

1. U.S Patent No: 5,246,937 (“ 937 patent”)；
2. U.S Patent No: 5,840,763 (“ 763 patent”)；
3. U.S Patent No: 5,866,581 (“ 581 patent”) ；
4. U.S Patent No: 5,916,893 (“ 893 patent”) ；
5. U.S Patent No: 6,124,304 (“ 304 patent”) ；

其中，937 patent 與 Famvir®的原料藥(Active Ingredient) famciclovir 有關，至於其餘登錄於橘皮書的專利，則是與使用 Famvir®的治療方法有關的方法專利(method patents)。此外，937 patent 的專利期限至 2012 年，但相關治療方法的專利到期日則為 2014~2015 間。

(二) 訴訟案背景資料及裁定結果概述

而在 2004 年，TEVA 公司向 FDA 提出 famciclovir 學名藥之 ANDA(Abbreviated New Drug Application) 藥證申請，並依據 paragraph IV of 21 U.S.C. § 355(j)(2)(A)(vii) 試驗免責之相關規定，主張其學名藥並未侵犯 Novartis 登錄於橘皮書中相關 Famvir®的五項專利，或是主張前述專利無效。

而 TEVA 的第四類學名藥認證書(paragraph IV certifications)中，構成在 35 U.S.C. §271(e)(1)的技術侵權，NOVARTIS 亦必須針對被侵權的專利，依據 21

U.S.C.§355(j)(5)(B)(iii)的規定，在 45 天內向 TEVA 提出告訴，以便能獲得 FDA 自動停止審查 30 個月的 statutory mandate，並立刻延遲 FDA 發給 TEVA 的 famciclovir ANDA 藥證。

Novartis 亦只單獨針對 937 patent，向 Teva 提出侵權告訴，亦即並未包含 Novartis 其他相關治療方法的專利侵權訴訟。此侵權訴訟在 New Jersey 州地方法院進行訴訟審理，訴案名稱之案號為：Novartis Pharm. Corp., v. Teva Pharm. USA, Inc., No. 05-1887 (D .N.J.2005)。

而在 Novartis 公司提出訴案之後，Teva 公司依據 21 U.S.C. § 355(j)(5)(C)及 35 U.S.C. § 271(e)(5)之法規，針對其餘四項方法專利提出確認之訴(declaratory judgment)，以建立專利確定性 (patent certainty)。而前述之法條〔Title 21 U.S.C. § 355(j)(5)(C)〕，為 2003 年針對 ANDA statute 所提出之修正案：藉由民事訴訟獲得專利確定性(civil action to obtain patent certainty)。在這一修正條文中明載，專利權所有人或是 NDA 所有人必須採行的回應措施，亦即其在收到通知有學名藥廠申請第四類學名藥認證書的申請時，若是未在 45 天內提出侵權訴訟，ANDA 申請人即可提出確認之訴的民事訴訟，亦即可主張該有爭議的專利是屬無效，或是所申請之 ANDA 學名藥並未侵權。而在 2003 年關於 ANDA 的另一修正條文 Title 35 U.S.C. § 271(e)(5)中，也是關聯於專利權條款中，得以民事訴訟方式獲得專利確定性；而聯邦法院考量與憲法的一致性，並可依據 title 28 的§ 2201 法條中，得對於任何確認之訴案，主張擁有關於 Subject Matter 的管轄權，以及判定該有爭議的專利是屬無效或是並未侵權。

TEVA 亦辯稱當 NOVARTIS 一開始只針對 937 Patent 向其提出訴訟時，NOVARTIS 即已企圖將 TEVA 推向苛刻的因應選項中，其一是當 937 patent 一到期，或是 TEVA 在等待侵權訴訟結果時，TEVA 即甘冒專利侵權的重大責任將產品上市；另外則是 TEVA 放棄上市機會，讓 NOVARTIS 有效的延長其使用 937 patent 的時間。

NOVARTIS 亦請求法院駁回其缺少 subject matter 管轄權之訴因，以及辯稱 TEVA 沒有合理的論點，說明其會被 NOVARTIS 控告侵害前述的四項方法專利。而 TEVA 所提的回覆中則辯稱以下四個論點：

1. NOVARTIS已經針對其成份專利(Composition Patent)向TEVA提出控告；
2. 橘皮書中所列專利會構成法律侵權；
3. NOVARTIS經常對學名藥廠提出訴訟；
4. NOVARTIS向TEVA提出不控告之協議。

但地方法院的判決(Teva Pharm., USA, Inc., v. Novartis Pharm. Corp., No.

05-2881, slip op. at 10 (D.N.J. Dec. 12, 2005))駁回TEVA之請求，TEVA並未於地院取得前述四項方法專利之專利確定性的確認之訴。地方法院主要是引用*Pfizer*案(Pfizer, 395 F.3d at 1332)中的兩叉試驗法(two prong test)，亦即ANDA原告提出確認之訴時，必須證明兩個要件：

1. 合理的憂慮專利權所有人即將提出侵權控訴；
2. 已有侵權活動或企圖侵權。

而經由比較本案事實與*Pfizer*案之後，地方法院發現TEVA並未能證明已有合理憂慮到侵權控訴，所以地方法院因此主張缺乏對確認之訴案的管轄權，而予以駁回。

但TEVA上訴到聯邦巡迴法庭後，該法庭則依法規28 U.S.C. § 1295(a)(1)，主張地方法院以缺乏管轄權而駁回TEVA的確認之訴是不適當的，因為聯邦法庭認為認為本案的爭訟是屬於法律問題，地院其實是擁有管轄權的。

(三) 對台灣學名藥廠的影響與建議

學名藥廠的專利佈局策略，並不會將所有專利都放置在橘皮書中，以便在興訟過程做為學名藥廠侵權的有利政策，以便利用訴訟達成延長專賣權時間的目的；學名藥廠則可利用舉發專利藥廠之專利無效，或是向法院提請專利確認之訴，以達成盡快上市的目的。

三、PFIZER INC. v. DR. REDDY'S LABORATORIES 案對台灣學名藥廠發展之影響

本案係輝瑞藥廠(Pfizer, Inc.)控告 DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., 侵權，地方法院 Mayer 法官判侵權不成立，但是聯邦巡迴上訴法院 Newman 法官推翻地方法院判決，以下是本案主要的攻防內涵及引用法條，及其對台灣學名藥廠發展的影響。

(一) 訴訟標的

輝瑞藥廠(Pfizer, Inc.)上訴聯邦巡迴法院，乃因地方法院判決 DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., 侵權未成立，主要訴訟標的為；Dr. Reddy's 依據 21U.S.C.§355(b)(2)在 2001 年 12 月申請新藥 Paper NDA, 企圖行銷 amlodipine as the maleate salt，但其使用則為 Pfizer 申請並已經獲得 FDA 許可(909 專利)，Dr. Reddy's 知道 amlodipine maleate 已經包含在 909 專利中，但是 Dr. Reddy's 認為期限延長僅限於 besylate salt，乃因為其是註冊產品。

(二) 訴訟案背景資料及裁定結果概述

地方法院認同 Dr. Reddy's 的觀點，但是聯邦巡迴上訴法院 Newman 及 Lourie 法官認為"909 專利"的延長期限有包括申請時的第 1,7,8 項 r 及§156f 中的 amlodipine and any salt or ester, 因此認定侵權成立。其主要的理由如下：地方法院所引用 35 U.S.C.§156(b)來限制 FDA 核准的產品的專利條件，Newman 法官不同意，乃因地方法院指出 156(f)定義產品是一個新藥，"其包含主要成分的任何 salt or ester"，地方法院未考慮，不管任何在 156(f)所定義之產品均適用於專利延長條件，但是主審法官 Myaer 認為 35 U.S.C. § 156(a)(4)明定"該項產品再商業行銷或使用之前必須適用於一般審查其"，在本案產品中適用於一般審查期的是 amlodipine besylate，Dr. Reddy's 尋求在市場銷售的產品不僅包括 amlodipine,也包括 amlodipine maleate，就目前來看 amlodipine maleate 不算是符合專利延長條件，其也不適用於法規的適用條件。延長期限不適用前案，在 Merck v. Kessler, 80 F.3d 1543, 1547 (Fed. Cir. 1996)案例中，我們認為延長期限僅適用一個而不管當初申請時被核准的許多藥；而且若去解讀 section 156(b)(1)，本上訴案中，我們認為專利的延長期限不包括被專利保護的所有產品，而僅僅是被延長的產品而已，因此本案僅能適用於 amlodipine besylate 的保護。

(三) 對台灣學名藥廠的影響與建議

台灣通常所製造的學名藥是國際大廠的藥，因此製造學名藥碰到被告是常有的事，通常需要打國際官司，除了所需的訴訟費用非常高，通常約需美金二百萬元到六百萬元不等，且由本案發覺即使打官司，由於訴訟變數太大，勝算也不大。

陸、台灣發展學名藥之策略

前幾章已經就美國與台灣藥品法律規章作研析，更對最近的案例加以研析，已經充分理解美國政府對其法令之態度，更進而理解美國大藥廠的訴訟策略，再與美國大律師事務所的律師作對談及參觀相當成功的學名藥廠高階主管對談，了解其經營的模式與策略，本章將就所得結果，提出對台灣發展學名藥的策略供業者與政府參考，相關訪談資料與問題如附錄四。

一、與律師對談資料研析與訴訟策略

(一) 學名藥廠挑戰專利藥廠之方式

1. Paragraph IV :

依據 Hatch & Waxman Act 中，為排除專利侵權的疑慮，在學名藥廠提出 ANDA 的申請時，必須證明欲申請之藥品並無侵犯同成份藥品的專利，而同成份藥品的專利資訊則是登錄於所謂「橘皮書」(Orange Book)上。因此學名藥廠必須提出以下四種證明之一，來說明其欲申請之藥品並無專利侵權的疑慮：所謂的四種證明即是：paragraph I 欲申請之學名藥並未有任何專利登錄於橘皮書中、paragraph II 雖有專利登錄於橘皮書，但專利已經過期、paragraph III 雖有專利登錄於橘皮書，但該專利即將到期，而學名藥廠會於該專利到期後再銷售學名藥、paragraph IV 雖有專利登錄於橘皮書中，但此一專利無效；或學名藥廠所申請 ANDA 藥品，並無侵害已登錄的專利權。由於前三種情況不是無專利權、專利權過期，就是學名藥廠將會等待其專利權過期，並不會有專利侵害的疑慮。當學名藥廠可以舉發專利藥廠的專利無效，或是學名藥廠可以舉證自己的產品並沒有侵害專利權時，即可提出 ANDA 的申請。在學名藥廠提出申請的同時，亦要通知專利藥廠其專利無效或是沒有侵害專利的事實，專利藥廠則可在接獲通知後 45 日之內提出專利侵權訴訟，除了可以中斷 FDA 的審查程序 30 個月外，亦可以針對學名藥廠藥品是否有專利侵害於法院中做出判決，此即是所謂的 paragraph IV patent challenge。

2. Reexamination :

時間花費較長，但費用較便宜。

3. Reissue :

時間需花費多久較不確定，但尚未有藥廠的案例。

(二) 做好 Due diligence 最重要

2. 可觀察對方多久完成 prosecution。
3. 該藥品有沒有 benefit 可以 cover 所有開支之費用。
4. 可尋求 second opinion。

(三) 其他相關措施

1. 有登錄在 Orange Book 之專利藥廠才能擁有 30 天中止 FDA 審查學名藥證之權利。
2. 學名藥廠先前小心選擇標的最重要。
3. 學名藥廠事前先準備再出擊可以降低自己的律師費用。
4. 研發初期先做好內部 examination 過幾年後再做外部 examination。

(四) 建議策略

針對美國學名藥廠應如何進行專利訴訟的準備，首先應針對橘皮書之專利作分析及拆解，可採用二個方式：

1. 做橘皮書上所列的專利無效，包括：
   a. 舉發專利無效(Invalidation)；
   b. 再審查程序(Reexamination)；
   c. 再公告程序(Reissue)。
2. 迴避其專利申請範圍。

至於如何迴避其專利申請範圍？進行這樣的研發之前，可以經由分析專利範圍及分析其專利申請歷史(file wrapper)中著手，針對以下部份作迴避，例如文義侵害的部份、專利範圍的均等性(the doctrine of equivalents)、專利申請過程中未敘明的元件、禁反言(prosecution history estoppel)的部份來進行研發。

由於學名藥廠要針對其化合物專利進行突破，並非容易的事，而且，如果把化合物專利進行舉發的話，其他的學名藥廠亦會跟進，因為化合物專利如果被舉發之後，其專利權即自始不存在，故其亦不可能造成其他藥廠的進入障礙。因此學名藥廠較佳的作法其實是在迴避專利藥廠的專利之外，還可以產生一些新的專利來保護自己的產品，例如使用不同的劑型專利來保護，如果專利藥廠的原本產品是注射的劑型，則學名藥廠可以採用口服的劑型來創造障礙，同時也不會有專利侵權的疑慮，同時也可以阻礙其他的藥廠進入這個相同產品的市場。

二、名藥廠高階主管訪談資料研析與經營策略(請參閱附錄五)

此次非常幸運能參觀一家經營非常成功的學名藥廠 IMPAX 公司，從其公司規模與經營績效來看，與其對談可以得到寶貴經驗、經營策略、及商業模式，下列是其主要內涵。

(一) 不建議台灣藥廠繼續做一般之 generic 而應該做 super generic

其主要的理由如下：

1. 台灣公司目前均無經費打訴訟。
2. 印度以及大陸的競爭對手強，除非做 controlled-release(但是現在越來越多公司在做這方面)。(印度藥廠之 R&D 人數平均共 1,500-2,000 人，平均薪資為 US$ 1,000)

(二) IMPAX 公司策略與決策流程

1. Formulation 之發展經驗：

(1)Alza 之方式：有了 idea 後進行 dosage form 之發展，再拿出來賣掉，此方式許總也做過，知道非常的辛苦，且 R&D 很花錢，10 個產品中僅有 1 個會成功(沒錢)。

(2)IMPAX 之方式：先找出目標產品，再做技術開發，且不愛 license。

2. 決策流程：

(1) Marketing Planning：此為非常重要之團隊(generic 以及 branded 部門各有自己的團隊)，放於 R&D 以及 sales marketing 部門之間，主要為科學家轉而進行 business marketing。此團隊成員包括 R&D、marketing 以及 legal，共約 5-6 人。

(2) 團隊先 identify 目標產品→amend need→literature 查詢→PK 人員確認有無發展之可能性→團隊將目標以及理由交由總經理決策→R&D 正式進行開發；此流程可預估出未來該產品發展之長相。

(3) Compound patent 不碰，其他的均可，不怕打訴訟。

(4) 專利逾期前 5-7 年即開始做，時間點之選擇極為重要，太早或太晚都不行。

3. IP management 極為重要且嚴格，

目前將於台灣設立的廠區，並不會在台灣上市產品，目標還是美國市場所以才設廠於台灣(若市場目標是台灣，廠區將會設在大陸)，相關 IP 管理還是由總公司來進行。

三.台灣發展學名要之策略

經過以上訪談後，深感台灣學名藥之發展確實有一段崎嶇路要走，假使策略正確將會有發展機會，以下是討論分析後建議之策略：

(一) 不發展一般學名藥(generic)，而是發展上等學名藥(super generic)

(二) 政府應該積極制定適合學名藥廠發展的法規與政策

(三) 透過國內外藥廠併購來增加研發能量與市場實力

(四) 購買或入股國際專利藥廠強化技術能量，全力發展上等學名要與 controlled-release

柒、結論與建議

台灣之學名藥狀況，由於市場並不大且有特殊之全民健康保險制度，另外相關法規之規範極不完善，也因此台灣之學名藥廠必須有自己之營運發展策略；此方面，接受訪談的許總經理則建議台灣之學名藥廠不應繼續發展一般學名藥，而需要開發上等學名藥 super generic 以迎戰市場；事實上，目前台灣之製藥產業其水準已達國際標準，台灣之學名藥也已有外銷至歐、美、日等製藥先進國家之交易進行中，製藥實力已受證明。故台灣學名藥廠如何跨出，除自己之策略建構之外，主要還需要政府法規以及政策之支持，因此推動學名藥之相關完善法規應是極為重要且急迫之事。

根據對法規與訴訟案例的研析，我們認為台灣的藥廠不應再以生產學名藥為主，因為面臨訴訟時無力負擔訴訟費用，更無法與國際大廠抗衡，但是當面對訴訟十也不應該慌張，應該做好準備應戰，否則就應該尋求和解或做為其代工廠。另外跟律師與學名藥廠高階主管對談後，發現同樣的結論，即訴訟很費時費錢，台灣藥廠規模小，無法負擔，因此必須要尋找自己的利基來發展，例如做為代工及發展上等學名藥(super generic)等。本研究案，我們得到以下結論，期盼政府與藥界共同努力，發展屬於台灣的藥品：

1. 找到利基產品，發展劑型藥；
2. 強化研發能量與團隊；
3. 面對訴訟要做好準備；
4. 公司要做好專利管理工作；
5. 政府要積極修法，營造適合發展的環境，如人體試驗等；
6. 國內藥廠應該積極整併，發展自己的產品對抗競爭；
7. 積極尋找合作對象，擴充通路，為產品尋找出路；
8. 生技公司應與製藥廠密切合作；
9. 強化產學合作，積極發展製藥產業。可從以下五方面著手：
   (1)專注國內常見疾病，找出新生物標定物，配合電子產業，開發新試劑與儀器；
   (2)開發差異化學名藥或舊藥新用；
   (3)控制品質與成本，提升競爭力；
   (4)積極與國際大廠合作，訓練研發製造與行銷人才；
   (5)積極訓練領導與管理人才。

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附錄

一、台灣藥品法規

(一)藥事法

第 一 章 總則

第 1 條　藥事之管理，依本法之規定；本法未規定者，依其他有關法律之規定。但管制藥品管理條例有規定者，優先適用該條例之規定。
前項所稱藥事，指藥物、藥商、藥局及其有關事項。

第 2 條　本法所稱衛生主管機關：在中央為行政院衛生署；在直轄市為直轄市政府；在縣（市）為縣（市）政府。

第 3 條　中央衛生主管機關得專設藥物管理機關，直轄市及縣（市）衛生主管機關於必要時亦得報准設置。

第 4 條　本法所稱藥物，係指藥品及醫療器材。

第 5 條　本法所稱試驗用藥物，係指醫療效能及安全尚未經證實，專供動物毒性藥理評估或臨床試驗用之藥物。

第 6 條　本法所稱藥品，係指左列各款之一之原料藥及製劑：
一、載於中華藥典或經中央衛生主管機關認定之其他各國藥典、公定之國家處方集，或各該補充典籍之藥品。
二、未載於前款，但使用於診斷、治療、減輕或預防人類疾病之藥品。
三、其他足以影響人類身體結構及生理機能之藥品。
四、用以配製前三款所列之藥品。

第 7 條　本法所稱新藥，係指經中央衛生主管機關審查認定屬新成分、新療效複方或新使用途徑製劑之藥品。

第 8 條　本法所稱製劑，係指以原料藥經加工調製，製成一定劑型及劑量之藥品。製劑分為醫師處方藥品、醫師藥師藥劑生指示藥品、成藥及固有成方製劑。
前項成藥之分類、審核、固有成方製劑製售之申請、成藥及固有成方製劑販賣之管理及其他應遵行事項之辦法，由中央衛生主管機關定之。

第 9 條　本法所稱成藥，係指原料藥經加工調製，不用其原名稱，其摻入之藥品，不超過中央衛生主管機關所規定之限量，作用緩和，無積蓄性，耐久儲存，使用簡便，並明示其效能、用量、用法，標明成藥許可證字號，其使用不待醫師指示，即供治療疾病之用者。

第 10 條　本法所稱固有成方製劑，係指依中央衛生主管機關選定公告具有醫療效能之傳統中藥處方調製（劑）之方劑。

第 11 條　本法所稱管制藥品，係指管制藥品管理條例第三條規定所稱之管制藥品。

第 12 條　本法所稱毒劇藥品，係指列載於中華藥典毒劇藥表中之藥品；表中未列載者，由中央衛生主管機關定之。

第 13 條　本法所稱醫療器材，係包括診斷、治療、減輕或直接預防人類疾病，或足以影響人類身體結構及機能之儀器、器械、用具及其附件、配件、零件。
前項醫療器材，中央衛生主管機關應視實際需要，就其範圍、種類、管理及其他應管理事項，訂定醫療器材管理辦法規範之。

第 14 條　本法所稱藥商，係指左列各款規定之業者：
一、藥品或醫療器材販賣業者。
二、藥品或醫療器材製造業者。

第 15 條　本法所稱藥品販賣業者，係指左列各款規定之業者：
一、經營西藥批發、零售、輸入及輸出之業者。
二、經營中藥批發、零售、調劑、輸入及輸出之業者。

第 16 條　本法所稱藥品製造業者，係指經營藥品之製造、加工與其產品批發、輸出及自用原料輸入之業者。
前項藥品製造業者輸入自用原料，應於每次進口前向中央衛生主管機關申請核准後，始得進口；已進口之自用原料，非經中央衛生主管機關核准，不得轉售或轉讓。
藥品製造業者，得兼營自製產品之零售業務。

第 17 條　本法所稱醫療器材販賣業者，係指經營醫療器材之批發、零售、輸入及輸出之業者。
經營醫療器材租賃業者，準用本法關於醫療器材販賣業者之規定。

第 18 條　本法所稱醫療器材製造業者，係指製造、裝配醫療器材，與其產品之批發、輸出及自用原料輸入之業者。
前項醫療器材製造業者，得兼營自製產品之零售業務。

第 19 條　本法所稱藥局，係指藥師或藥劑生親自主持，依法執行藥品調劑、供應業務之處所。
前項藥局得兼營藥品零售業務。

第 20 條　本法所稱偽藥，係指藥品經稽查或檢驗有左列各款情形之一者：
一、未經核准，擅自製造者。
二、所含有效成分之名稱，與核准不符者。
三、將他人產品抽換或摻雜者。
四、塗改或更換有效期間之標示者。

第 21 條　本法所稱劣藥，係指核准之藥品經稽查或檢驗有左列情形之一者：
一、擅自添加非法定著色劑、防腐劑、香料、矯味劑及賦形劑者。

二、所含有效成分之質、量或強度，與核准不符者。

三、藥品中一部或全部含有污穢或異物者。

四、有顯明變色、混濁、沈澱、潮解或已腐化分解者。

五、主治效能與核准不符者。

六、超過有效期間或保存期限者。

七、因儲藏過久或儲藏方法不當而變質者。

八、裝入有害物質所製成之容器或使用回收容器者。

第 22 條 本法所稱禁藥，係指藥品有左列各款情形之一者：

一、經中央衛生主管機關明令公告禁止製造、調劑、輸入、輸出、販賣或陳列之毒害藥品。

二、未經核准擅自輸入之藥品。但旅客或隨交通工具服務人員攜帶自用藥品進口者，不在此限。

前項第二款自用藥品之限量，由中央衛生主管機關會同財政部公告之。

第 23 條 本法所稱不良醫療器材，係指醫療器材經稽查或檢驗有左列各款情形之一者：

一、使用時易生危險，或可損傷人體，或使診斷發生錯誤者。

二、含有毒質或有害物質，致使用時有損人體健康者。

三、超過有效期間或保存期限者。

四、性能或有效成分之質、量或強度，與核准不符者。

第 24 條 本法所稱藥物廣告，係指利用傳播方法，宣傳醫療效能，以達招徠銷售為目的之行為。

第 25 條 本法所稱標籤，係指藥品或醫療器材之容器上或包裝上，用以記載文字、圖畫或記號之標示物。

第 26 條 本法所稱仿單，係指藥品或醫療器材附加之說明書。

第 二 章 藥商之管理

第 27 條 凡申請為藥商者，應申請直轄市或縣 (市) 衛生主管機關核准登記，繳納執照費，領得許可執照後，方准營業；其登記事項如有變更時，應辦理變更登記。

前項登記事項，由中央衛生主管機關定之。

藥商分設營業處所或分廠，仍應依第一項規定，各別辦理藥商登記。

第 27-1 條 藥商申請停業，應將藥商許可執照及藥物許可證隨繳當地衛生主管機關，於執照上記明停業理由及期限，俟核准復業時發還之。每次停業期間不得超過一年，停業期滿未經當地衛生主管機關核准繼續停業者，應於停業期滿前三十日內申請復業。

藥商申請歇業時，應將其所領藥商許可執照及藥物許可證一併繳銷；其不繳銷者，由原發證照之衛生主管機關註銷。

藥商屆期不申請停業、歇業或復業登記，經直轄市或縣（市）衛生主管機關查核發現原址已無營業事實者，應由原發證照之衛生主管機關，將其有關證照註銷。

違反本法規定，經衛生主管機關處分停止其營業者，其證照依第一項規定辦理。

第 28 條 西藥販賣業者之藥品及其買賣，應由專任藥師駐店管理。但不售賣麻醉藥品者，得由專任藥劑生為之。

中藥販賣業者之藥品及其買賣，應由專任中醫師或修習中藥課程達適當標準之藥師或藥劑生駐店管理。

西藥、中藥販賣業者，分設營業處所，仍應依第一項及第二項之規定。

第 29 條 西藥製造業者，應由專任藥師駐廠監製；中藥製造業者，應由專任中醫師或修習中藥課程達適當標準之藥師駐廠監製。

中藥製造業者，以西藥劑型製造中藥，或摻入西藥製造中藥時，除依前項規定外，應由專任藥師監製。

西藥、中藥製造業者，設立分廠，仍應依前二項規定辦理。

第 30 條 藥商聘用之藥師、藥劑生或中醫師，如有解聘或辭聘，應即另聘。

第 31 條 從事人用生物藥品製造業者，應聘用國內外大學院校以上醫藥或生物學等系畢業，具有微生物學、免疫學藥品製造專門知識，並有五年以上製造經驗之技術人員，駐廠負責製造。

第 32 條 醫療器材販賣或製造業者，應視其類別，聘用技術人員。

前項醫療器材類別及技術人員資格，由中央衛生主管機關定之。

第 33 條 藥商僱用之推銷員，應由該業者向當地之直轄市、縣（市）衛生主管機關登記後，方准執行推銷工作。

前項推銷員，以向藥局、藥商、衛生醫療機構、醫學研究機構及經衛生主管機關准予登記為兼售藥物者推銷其受僱藥商所製售或經銷之藥物為限，並不得有沿途推銷、設攤出售或擅將藥物拆封、改裝或非法廣告之行為。

第 三 章 藥局之管理及藥品之調劑

第 34 條 藥局應請領藥局執照，並於明顯處標示經營者之身分姓名。其設立、變更登記，準用第二十七條第一項之規定。

藥局兼營藥品零售業務，應適用關於藥商之規定。但無須另行請領藥商許可執照。

第 35 條 修習中藥課程達適當標準之藥師，親自主持之藥局，得兼營中藥之調劑、供應或零售業務。

第 36 條 藥師親自主持之藥局，具有鑑定設備者，得執行藥品之鑑定業務。

第 37 條 藥品之調劑，非依一定作業程序，不得為之；其作業準則，由中央衛生主

管機關定之。

前項調劑應由藥師為之。但不含麻醉藥品者，得由藥劑生為之。

醫院中之藥品之調劑，應由藥師為之。但本法八十二年二月五日修正施行前已在醫院中服務之藥劑生，適用前項規定，並得繼續或轉院任職。

中藥之調劑，除法律另有規定外，應由中醫師監督為之。

第 38 條　藥師法第十二條、第十六條至第二十條之規定，於藥劑生調劑藥品時準用之。

第 四 章 藥物之查驗登記

第 39 條　製造、輸入藥品，應將其成分、規格、性能、製法之要旨，檢驗規格與方法及有關資料或證件，連同原文和中文標籤、原文和中文仿單及樣品，並繳納費用，申請中央衛生主管機關查驗登記，經核准發給藥品許可證後，始得製造或輸入。

向中央衛生主管機關申請藥品試製經核准輸入原料藥者，不適用前項規定；其申請條件及應繳費用，由中央衛生主管機關定之。

第一項輸入藥品，應由藥品許可證所有人及其授權者輸入。

申請第一項藥品查驗登記、依第四十六條規定辦理藥品許可證變更、移轉登記及依第四十七條規定辦理藥品許可證展延登記、換發及補發，其申請條件、審查程序、核准基準及其他應遵行之事項，由中央衛生主管機關以藥品查驗登記審查準則定之。

第 40 條　製造、輸入醫療器材，應向中央衛生主管機關申請查驗登記並繳納費用，經核准發給醫療器材許可證後，始得製造或輸入。

前項輸入醫療器材，應由醫療器材許可證所有人或其授權者輸入。

申請醫療器材查驗登記、許可證變更、移轉、展延登記、換發及補發，其申請條件、審查程序、核准基準及其他應遵行之事項，由中央衛生主管機關定之。

第 40-1 條　中央衛生主管機關為維護公益之目的，於必要時，得公開所持有及保管藥商申請製造或輸入藥物所檢附之藥物成分、仿單等相關資料。但對於藥商申請新藥查驗登記屬於營業秘密之資料，應保密之。

前項得公開事項之範圍及方式，其辦法由中央衛生主管機關定之。

第 40-2 條　中央衛生主管機關於核發新藥許可證時，應公開申請人檢附之已揭露專利字號或案號。

新成分新藥許可證自核發之日起五年內，其他藥商非經許可證所有人同意，不得引據其申請資料申請查驗登記。

新成分新藥許可證核發之日起三年後，其他藥商得依本法及相關法規有關藥品查驗登記審查之規定提出同成分、同劑型、同劑量及同單位含量藥品之查驗登記申請，符合規定者，得於新成分新藥許可證核發屆滿五年之翌

日起發給藥品許可證。

新成分新藥在外國取得上市許可後三年內，必須向中央衛生主管機關申請查驗登記，始得準用第二項之規定。

新藥專利權不及於藥商申請查驗登記前所進行之研究、教學或試驗。

第 41 條 為提昇藥物製造工業水準，對於藥物科技之研究發展，得由中央衛生主管機關會同中央工業主管機關獎勵之。

前項獎勵之資格條件、審議程序及其他應遵行事項之辦法，由中央衛生主管機關會同中央工業主管機關定之。

第 42 條 中央衛生主管機關對於製造、輸入之藥物，應訂定作業準則，作為核發、變更及展延藥物許可證之基準。

前項作業準則，由中央衛生主管機關定之。

第 43 條 製造、輸入藥物之查驗登記申請書及輸出藥物之申請書，其格式、樣品份數、有關資料或證書費、查驗費之金額，由中央衛生主管機關定之。

第 44 條 試驗用藥物，應經中央衛生主管機關核准始得供經核可之教學醫院臨床試驗，以確認其安全與醫療效能。

第 45 條 經核准製造或輸入之藥物，中央衛生主管機關得指定期間，監視其安全性。

藥商於前項安全監視期間應遵行事項，由中央衛生主管機關定之。

第 45-1 條 醫療機構、藥局及藥商對於因藥物所引起之嚴重不良反應，應行通報；其方式、內容及其他應遵行事項之辦法，由中央衛生主管機關定之。

第 46 條 經核准製造、輸入之藥物，非經中央衛生主管機關之核准，不得變更原登記事項。

經核准製造、輸入之藥物許可證，如有移轉時，應辦理移轉登記。

第 47 條 藥物製造、輸入許可證有效期間為五年，期滿仍須繼續製造、輸入者，應事先申請中央衛生主管機關核准展延之。但每次展延，不得超過五年。屆期未申請或不准展延者，註銷其許可證。

前項許可證如有污損或遺失，應敘明理由，申請原核發機關換發或補發，並應將原許可證同時繳銷，或由核發機關公告註銷。

第 48 條 藥物於其製造、輸入許可證有效期間內，經中央衛生主管機關重新評估確定有安全或醫療效能疑慮者，得限期令藥商改善，屆期未改善者，廢止其許可證。但安全疑慮重大者，得逕予廢止之。

第 48-1 條 第三十九條第一項製造、輸入藥品，應標示中文標籤、仿單或包裝，始得買賣、批發、零售。但經中央衛生主管機關認定有窒礙難行者，不在此限。

第 五 章 藥物之販賣及製造

第 49 條 藥商不得買賣來源不明或無藥商許可執照者之藥品或醫療器材。

第 50 條 須由醫師處方之藥品，非經醫師處方，不得調劑供應。但左列各款情形不在此限：

一、同業藥商之批發、販賣。

二、醫院、診所及機關、團體、學校之醫療機構或檢驗及學術研究機構之購買。

三、依中華藥典、國民處方選輯處方之調劑。

前項須經醫師處方之藥品，由中央衛生主管機關就中、西藥品分別定之。

第 51 條 西藥販賣業者，不得兼售中藥；中藥販賣業者，不得兼售西藥。但成藥不在此限。

第 52 條 藥品販賣業者，不得兼售農藥、動物用藥品或其他毒性化學物質。

第 53 條 藥品販賣業者輸入之藥品得分裝後出售，其分裝應依下列規定辦理：

一、製劑：申請中央衛生主管機關核准後，由符合藥品優良製造規範之藥品製造業者分裝。

二、原料藥：由符合藥品優良製造規範之藥品製造業者分裝；分裝後，應報請中央衛生主管機關備查。

前項申請分裝之條件、程序、報請備查之期限、程序及其他分裝出售所應遵循之事項，由中央衛生主管機關定之。

第 54 條 藥品或醫療器材經核准發給藥物輸入許可證後，為維護國家權益，中央衛生主管機關得加以管制。但在管制前已核准結匯簽證者，不在此限。

第 55 條 經核准製造或輸入之藥物樣品或贈品，不得出售。

前項樣品贈品管理辦法，由中央衛生主管機關定之。

第 56 條 經核准製售之藥物，如輸出國外銷售時，其應輸入國家要求證明文字者，應於輸出前，由製造廠商申請中央衛生主管機關發給輸出證明書。

前項藥物，中央衛生主管機關認有不敷國內需要之虞時，得限制其輸出。

第 57 條 製造藥物，應領有工廠登記證。但經中央衛生主管機關核准為研發而製造之藥物，不在此限。

藥物製造工廠或場所之設備及衛生條件，應符合藥物製造工廠設廠標準，經衛生及工業主管機關檢查合格後，始予核准登記；其廠址或場所遷移者，應申請變更登記。

藥物之製造符合中央衛生主管機關規定者，藥商得繳納費用，向中央衛生主管機關申領證明書。

藥物之國外製造廠，準用前二項之規定，並由中央衛生主管機關定期或依實際需要赴廠檢查之。

前四項之申請條件、審查程序、核准基準及其他應遵行之事項，由中央衛生主管機關會同中央工業主管機關定之。

第 57-1 條 從事藥物研發之機構或公司，其研發用藥物，應於符合中央衛生主管機關規定之工廠或場所製造。

前項工廠或場所非經中央衛生主管機關核准，不得兼製其他產品；其所製造之研發用藥物，非經中央衛生主管機關核准，不得使用於人體。

第 58 條 藥物工廠，非經中央衛生主管機關核准，不得委託他廠製造或接受委託製造藥物。

第 六 章 管制藥品及毒劇藥品之管理

第 59 條 西藥販賣業者及西藥製造業者，購存或售賣管制藥品及毒劇藥品，應將藥品名稱、數量，詳列簿冊，以備檢查。管制藥品並應專設櫥櫃加鎖儲藏。

管制藥品及毒劇藥品之標籤，應載明警語及足以警惕之圖案或顏色。

第 60 條 管制藥品及毒劇藥品，須有醫師之處方，始得調劑、供應。

前項管制藥品應憑領受人之身分證明並將其姓名、地址、統一編號及所領受品量，詳錄簿冊，連同處方箋保存之，以備檢查。

管制藥品之處方及調劑，中央衛生主管機關得限制之。

第 61 條 (刪除)

第 62 條 第五十九條及第六十條所規定之處方箋、簿冊，均應保存五年。

第 63 條 (刪除)

第 64 條 中藥販賣業者及中藥製造業者，非經中央衛生主管機關核准，不得售賣或使用管制藥品。

中藥販賣業者及中藥製造業者售賣毒劇性之中藥，非有中醫師簽名、蓋章之處方箋，不得出售；其購存或出售毒劇性中藥，準用第五十九條之規定。

第 七 章 藥物廣告之管理

第 65 條 非藥商不得為藥物廣告。

第 66 條 藥商刊播藥物廣告時，應於刊播前將所有文字、圖畫或言詞，申請中央或直轄市衛生主管機關核准，並向傳播業者送驗核准文件。原核准機關發現已核准之藥物廣告內容或刊播方式危害民眾健康或有重大危害之虞時，應令藥商立即停止刊播並限期改善，屆期未改善者，廢止之。

藥物廣告在核准登載、刊播期間不得變更原核准事項。

傳播業者不得刊播未經中央或直轄市衛生主管機關核准、與核准事項不符、已廢止或經令立即停止刊播並限期改善而尚未改善之藥物廣告。

接受委託刊播之傳播業者，應自廣告之日起六個月，保存委託刊播廣告者之姓名 (法人或團體名稱) 、身分證或事業登記證字號、住居所 (事務所或營業所) 及電話等資料，且於主管機關要求提供時，不得規避、妨礙或拒絕。

第 66-1 條 藥物廣告，經中央或直轄市衛生主管機關核准者，其有效期間為一年，自核發證明文件之日起算。期滿仍需繼續廣告者，得申請原核准之衛生主管機關核定展延之；每次展延之期間，不得超過一年。
前項有效期間，應記明於核准該廣告之證明文件。

第 67 條 須由醫師處方或經中央衛生主管機關公告指定之藥物，其廣告以登載於學術性醫療刊物為限。

第 68 條 藥物廣告不得以左列方式為之：
一、假借他人名義為宣傳者。
二、利用書刊資料保證其效能或性能。
三、藉採訪或報導為宣傳。
四、以其他不正當方式為宣傳。

第 69 條 非本法所稱之藥物，不得為醫療效能之標示或宣傳。

第 70 條 採訪、報導或宣傳，其內容暗示或影射醫療效能者，視為藥物廣告。

第 八 章 稽查及取締

第 71 條 衛生主管機關，得派員檢查藥物製造業者，販賣業者之處所設施及有關業務，並得出具單據抽驗其藥物，業者不得無故拒絕。但抽驗數量以足供檢驗之用者為限。
藥物製造業者之檢查，必要時得會同工業主管機關為之。
本條所列實施檢查辦法，由中央衛生主管機關會同中央工業主管機關定之。

第 72 條 衛生主管機關得派員檢查醫療機構或藥局之有關業務，並得出具單據抽驗其藥物，受檢者不得無故拒絕。但抽驗數量以足供檢驗之用者為限。

第 73 條 直轄市、縣 (市) 衛生主管機關應每年定期辦理藥商及藥局普查。
藥商或藥局對於前項普查，不得拒絕、規避或妨礙。

第 74 條 依據微生物學、免疫學學理製造之血清、抗毒素、疫苗、類毒素及菌液等，非經中央衛生主管機關於每批產品輸入或製造後，派員抽取樣品，經檢驗合格，並加貼查訖封緘，不得銷售。檢驗封緘作業辦法，由中央衛生主管機關定之。。
前項生物藥品之原液，其輸入以生物藥品製造業者為限。

第 75 條 藥物之標籤、仿單或包裝，應依核准，分別刊載左列事項：
一、廠商名稱及地址。
二、品名及許可證字號。
三、批號。
四、製造日期及有效期間或保存期限。
五、主要成分含量、用量及用法。

六、主治效能、性能或適應症。

七、副作用、禁忌及其他注意事項。

八、其他依規定應刊載事項。

前項第四款經中央衛生主管機關明令公告免予刊載者，不在此限。

第 76 條 經許可製造、輸入之藥物，經發現有重大危害時，中央衛生主管機關除應隨時公告禁止其製造、輸入外，並廢止其藥物許可證；其已製造或輸入者，應限期禁止其輸出、調劑、販賣、供應、運送、寄藏、牙保、轉讓或意圖販賣而陳列，必要時並得沒入銷燬之。

第 77 條 直轄市或縣 (市) 衛生主管機關，對於涉嫌之偽藥、劣藥、禁藥或不良醫療器材，就偽藥、禁藥部分，應先行就地封存，並抽取樣品予以檢驗後，再行處理；就劣藥、不良醫療器材部分，得先行就地封存，並抽取樣品予以檢驗後，再行處理。其對衛生有重大危害者，應於報請中央衛生主管機關核准後，沒入銷燬之。

前項規定於未經核准而製造、輸入之醫療器材，準用之。

第 78 條 經稽查或檢驗為偽藥、劣藥、禁藥及不良醫療器材，除依本法有關規定處理外，並應為左列處分：

一、製造或輸入偽藥、禁藥及頂替使用許可證者，應由原發證照機關，廢止其全部製造、輸入許可證、工廠登記證及營業許可執照。

二、販賣或意圖販賣而陳列偽藥、禁藥者，由直轄市或縣 (市) 衛生主管機關，登報公告其商號、地址、負責人姓名、藥品名稱及所犯情節；再次違反者，得停止其營業。

三、製造、輸入、販賣或意圖販賣而陳列劣藥、不良醫療器材者，由直轄市或縣 (市) 衛生主管機關，登報公告其商號、地址、負責人姓名、藥物名稱及所犯情節；其情節重大或再次違反者，得廢止其各該許可證及停止其營業。

前項規定於未經核准而製造、輸入之醫療器材，準用之。'

第 79 條 查獲之偽藥或禁藥，沒入銷燬之。

查獲之劣藥或不良醫療器材，如係本國製造，經檢驗後仍可改製使用者，應由直轄市或縣 (市) 衛生主管機關，派員監督原製造廠商限期改製；其不能改製或屆期未改製者，沒入銷燬之；如係核准輸入者，應即封存，並由直轄市或縣 (市) 衛生主管機關責令原進口商限期退運出口，屆期未能退貨者，沒入銷燬之。

前項規定於經依法認定為未經核准而製造、輸入之醫療器材，準用之。

第 80 條 藥物有左列情形之一者，其製造或輸入之業者，應即通知醫療機構、藥局及藥商，並依規定期限收回市售品，連同庫存品一併依本法有關規定處理：

一、原領有許可證，經公告禁止製造或輸入者。

二、經依法認定為偽藥、劣藥或禁藥者。

三、經依法認定為不良醫療器材或未經核准而製造、輸入之醫療器材者。

四、製造、輸入藥物許可證未申請展延或不准展延者。

五、包裝、標籤、仿單經核准變更登記者。

六、其他經中央衛生主管機關公告應收回者。

製造、輸入業者收回前項各款藥物時，醫療機構及藥商應予配合。

第 81 條 舉發或緝獲偽藥、劣藥、禁藥及不良醫療器材，應予獎勵。

第 九 章 罰則

第 82 條 製造或輸入偽藥或禁藥者，處十年以下有期徒刑，得併科新臺幣一千萬元以下罰金。

犯前項之罪，因而致人於死者，處無期徒刑或十年以上有期徒刑，致重傷者，處七年以上有期徒刑。

因過失犯第一項之罪者，處三年以下有期徒刑、拘役或科新臺幣五十萬元以下罰金。

第一項之未遂犯罰之。

第 83 條 明知為偽藥或禁藥，而販賣、供應、調劑、運送、寄藏、牙保、轉讓或意圖販賣而陳列者，處七年以下有期徒刑，得併科新臺幣五百萬元以下罰金。

犯前項之罪，因而致人於死者，處七年以上有期徒刑，致重傷者，處三年以上十二年以下有期徒刑。

因過失犯第一項之罪者，處二年以下有期徒刑、拘役或科新臺幣三十萬元以下罰金。

第一項之未遂犯罰之。

第 84 條 未經核准擅自製造或輸入醫療器材者，處三年以下有期徒刑，得併科新台幣十萬元以下罰金。

明知為前項之醫療器材而販賣、供應、運送、寄藏、牙保、轉讓或意圖販賣而陳列者，依前項規定處罰之。

因過失犯前項之罪者，處六月以下有期徒刑、拘役或新台幣五萬元以下罰金。

第 85 條 製造或輸入第二十一條第一款之劣藥或第二十三條第一款、第二款之不良醫療器材者，處一年以下有期徒刑或拘役，得併科新台幣三萬元以下罰金。

因過失犯前項之罪或明知為前項之劣藥或不良醫療器材，而販賣、供應、調劑、運送、寄藏、牙保、轉讓或意圖販賣而陳列者，處六月以下有期徒刑或拘役，得併科新台幣一萬元以下罰金。

因過失而販賣、供應、調劑、運送、寄藏、牙保、轉讓或意圖販賣而陳列

第一項之劣藥或不良醫療器材者，處拘役或新台幣一萬元以下罰金。

第 86 條 擅用或冒用他人藥物之名稱、仿單或標籤者，處一年以下有期徒刑、拘役或科或併科新台幣五萬元以下罰金。

明知為前項之藥物而輸入、販賣、供應、調劑、運送、寄藏、牙保、轉讓或意圖販賣而陳列者，處六月以下有期徒刑、拘役或科或併科新台幣三萬元以下罰金。

第 87 條 法人之代表人，法人或自然人之代理人、受雇人，或其他從業人員，因執行業務，犯第八十二條至第八十六條之罪者，除依各該條規定處罰其行為人外，對該法人或自然人亦科以各該條之罰金。

第 88 條 依本法查獲供製造、調劑偽藥、禁藥之器材，不問屬於犯人與否，沒收之。

第 89 條 公務員假借職務上之權力、機會或方法，犯本章各條之罪或包庇他人犯本章各條之罪者，依各該條之規定，加重其刑至二分之一。

第 90 條 製造或輸入第二十一條第二款至第八款之劣藥或第二十三條第三款、第四款之不良醫療器材者，處新台幣六萬元以上三十萬元以下罰鍰。

販賣、供應、調劑、運送、寄藏、牙保、轉讓或意圖販賣而陳列前項之劣藥或不良醫療器材者，處新台幣三萬元以上十五萬元以下罰鍰。

犯前二項規定之一者，對其藥物管理人、監製人，亦處以各該項之罰鍰。

第 91 條 違反第六十五條或第八十條第一項第一款至第三款規定之一者，處新臺幣二十萬元以上五百萬元以下罰鍰。

違反第六十九條規定者，處新臺幣六十萬元以上二千五百萬元以下罰鍰，其違法物品沒入銷燬之。

第 92 條 違反第二十七條第一項、第三項、第二十九條、第三十一條、第三十六條、第三十七條第二項、第三項、第三十九條第一項、第四十條第一項、第四十四條、第四十五條之一、第四十六條、第四十九條、第五十條第一項、第五十一條至第五十三條、第五十五條第一項、第五十七條第一項至第四項、第五十七條之一、第五十八條、第五十九條、第六十條、第六十四條、第七十一條第一項、第七十二條、第七十四條、第七十五條規定之一者，處新臺幣三萬元以上十五萬元以下罰鍰。

違反第五十九條規定，或調劑、供應毒劇藥品違反第六十條第一項規定者，對其藥品管理人、監製人，亦處以前項之罰鍰。

違反第五十七條第二項至第四項規定者，除依第一項規定處罰外，當地衛生主管機關得公布藥廠或藥商名單及限期令其改善；屆期未改善者，得停止其營業，其藥物許可證並不准展延或不予受理其製造廠其他藥物之新申請案件，情節重大者，並得廢止已核准之許可證。

違反第六十六條第一項、第二項、第六十七條、第六十八條規定之一者，

處新臺幣二十萬元以上五百萬元以下罰鍰。

第 93 條 違反第十六條第二項、第二十八條、第三十條、第三十二條第一項、第三十三條、第三十七條第一項、第三十八條或第六十二條規定之一，或有左列情形之一者，處新臺幣三萬元以上十五萬元以下罰鍰：

一、成藥、固有成方製劑之製造、標示及販售違反中央衛生主管機關依第八條第三項規定所定辦法。

二、醫療器材之分級及管理違反中央衛生主管機關依第十三條第二項規定所定辦法。

三、藥物樣品、贈品之使用及包裝違反中央衛生主管機關依第五十五條第二項規定所定辦法。

違反第十六條第二項或第三十條規定者，除依前項規定處罰外，衛生主管機關並得停止其營業。

第 94 條 違反第三十四條第一項、第七十三條第二項、第八十條第一項第四款至第六款或第二項規定之一者，處新台幣二萬元以上十萬元以下罰鍰。

第 95 條 傳播業者違反第六十六條第三項規定者，處新臺幣二十萬元以上五百萬元以下罰鍰，其經衛生主管機關通知限期停止而仍繼續刊播者，處新臺幣六十萬元以上二千五百萬元以下罰鍰，並應按次連續處罰，至其停止刊播為止。

傳播業者違反第六十六條第四項規定者，處新臺幣六萬元以上三十萬元以下罰鍰，並應按次連續處罰。

第 96 條 違反第七章規定之藥物廣告，除依本章規定處罰外，衛生主管機關得登報公告其負責人姓名、藥物名稱及所犯情節，情節重大者，並得廢止該藥物許可證；其原品名二年內亦不得申請使用。

前項經廢止藥物許可證之違規藥物廣告，仍應由原核准之衛生主管機關責令該業者限期在原傳播媒體同一時段及相同篇幅刊播，聲明致歉。屆期未刊播者，翌日起停止該業者之全部藥物廣告，並不再受理其廣告之申請。

第 96-1 條 藥商違反第四十八條之一規定者，處新臺幣六萬元以上三十萬元以下罰鍰；其經衛生主管機關通知限期改善而仍未改善者，加倍處罰，並得按次連續處罰，至其改善為止。

第 97 條 藥商使用不實資料或證件，辦理申請藥物許可證之查驗登記、展延登記或變更登記時，除撤銷該藥物許可證外，二年內不得申請該藥物許可證之查驗登記；其涉及刑事責任者，並移送司法機關辦理。

第 97-1 條 依藥品查驗登記審查準則及醫療器材查驗登記審查準則提出申請之案件，其送驗藥物經檢驗與申請資料不符者，中央衛生主管機關自檢驗結果確定日起六個月內，不予受理其製造廠其他藥物之新申請案件。

前項情形於申復期間申請重新檢驗仍未通過者，中央衛生主管機關自重新

檢驗結果確定日起一年內，不予受理其製造廠其他藥物之新申請案件。

第 98 條 （刪除）

第 99 條 依本法規定處罰之罰鍰，受罰人不服時，得於處罰通知送達後十五日內，以書面提出異議，申請復核。但以一次為限。

科處罰鍰機關應於接到前項異議書後十五日內，將該案重行審核，認為有理由者，應變更或撤銷原處罰。

受罰人不服前項復核時，得依法提起訴願及行政訴訟。

第 99-1 條 依本法申請藥物查驗登記、許可證變更、移轉及展延之案件，未獲核准者，申請人得自處分書送達之日起四個月內，敘明理由提出申復。但以一次為限。

中央衛生主管機關對前項申復認有理由者，應變更或撤銷原處分。

申復人不服前項申復決定時，得依法提起訴願及行政訴訟。

第 100 條 本法所定之罰鍰，由直轄市、縣 (市) 衛生主管機關處罰之。

第 101 條 依本法應受處罰者，除依本法處罰外，其有犯罪嫌疑者，應移送司法機關處理。

第 一○ 章 附則

第 102 條 醫師以診療為目的，並具有本法規定之調劑設備者，得依自開處方，親自為藥品之調劑。

全民健康保險實施二年後，前項規定以在中央或直轄市衛生主管機關公告無藥事人員執業之偏遠地區或醫療急迫情形為限。

第 103 條 本法公布後，於六十三年五月三十一日前依規定換領中藥販賣業之藥商許可執照有案者，得繼續經營第十五條之中藥販賣業務。

八十二年二月五日前曾經中央衛生主管機關審核，予以列冊登記者，或領有經營中藥證明文件之中藥從業人員，並修習中藥課程達適當標準，得繼續經營中藥販賣業務。

前項中藥販賣業務範圍包括：中藥材及中藥製劑之輸入、輸出及批發；中藥材及非屬中醫師處方藥品之零售；不含毒劇中藥材或依固有成方調配而成之傳統丸、散、膏、丹、及煎藥。

上述人員、中醫師檢定考試及格或在未設中藥師之前曾聘任中醫師、藥師及藥劑生駐店管理之中藥商期滿三年以上之負責人，經修習中藥課程達適當標準，領有地方衛生主管機關證明文件；並經國家考試及格者，其業務範圍如左：

一、中藥材及中藥製劑之輸入、輸出及批發。

二、中藥材及非屬中醫師處方藥品之零售。

三、不含毒劇中藥材或依固有成方調配而成之傳統丸、散、膏、丹、及煎藥。

四、中醫師處方藥品之調劑。

前項考試，由考試院會同行政院定之。

第 104 條 民國七十八年十二月三十一日前業經核准登記領照營業之西藥販賣業者、西藥種商，其所聘請專任管理之藥師或藥劑生免受第二十八條第一項駐店管理之限制。

第 104-1 條 前條所稱民國七十八年十二月三十一日前業經核准登記領照營業之西藥販賣業者、西藥種商，係指其藥商負責人於七十九年一月一日以後，未曾變更且仍繼續營業者。但營業項目登記為零售之藥商，因負責人死亡，而由其配偶為負責人繼續營業者，不在此限。

第 104-2 條 依本法申請證照或事項或函詢藥品查驗登記審查準則及醫療器材查驗登記審查準則等相關規定，應繳納費用。

前項應繳費用種類及其費額，由中央衛生主管機關定之。

第 105 條 本法施行細則，由中央衛生主管機關定之。

第 106 條 本法自公布日施行。

本法中華民國八十六年五月七日修正公布之第五十三條施行日期，由行政院定之；中華民國九十五年五月五日修正之條文，自中華民國九十五年七月一日施行。

(二)藥事法施行細則

藥事法施行細則 (民國 94 年 02 月 16 日修正)

所有條文

第 1 條 本細則依藥事法 (以下簡稱本法) 第一百零五條規定訂定之。

第 2 條 本法第七條所稱新成分，係指新發明之成分可供藥用者；所稱新療效複方，係指已核准藥品具有新醫療效能，或兩種以上已核准成分之複方製劑具有優於各該單一成分藥品之醫療效能者；所稱新使用途徑，係指已核准藥品改變其使用途徑者。

第 3 條 本法第八條第二項所稱醫師處方藥品，係指經中央衛生主管機關審定，在藥品許可證上，載明須由醫師處方或限由醫師使用者。

第 4 條 本法所稱稽查，係指關於藥物有無經核准查驗登記及與原核准查驗登記或規定是否相符之檢查事項。

本法所稱檢驗，係指關於藥品之性狀、成分、質、量或強度等化驗鑑定事項，或醫療器材之化學、物理、機械、材質等鑑定事項。

第 5 條 本法第二十條第一款所稱未經核准，擅自製造者，不包括非販賣之研究、試製之藥品。

前項藥品應備有研究或試製紀錄，並以無商品化之包裝者為限。

第 6 條 本法第二十二條第二款所稱未經核准擅自輸入之藥品，係指該藥品未曾由中央衛生主管機關依本法第三十九條規定核發輸入許可證者。

第 7 條 本法第二十三條第一款所稱使用，係指依標籤或仿單刊載之用法，作正常合理之使用者。

第 8 條 本法第二十五條所稱標籤，包括直接標示於醫療器材上之文字、圖畫或記號。

第 9 條 本法第二十七條第二項規定藥商登記事項如左：

一、藥商種類。

二、營業項目。

三、藥商名稱。

四、地址。

五、負責人。

六、藥物管理、監製或技術人員。

七、其他應行登記事項。

第 10 條 依本法第二十七條第一項規定申請藥商登記者，應填具申請書，連同執照費及左列文件，申請直轄市或縣 (市) 衛生主管機關核准：

一、依本法規定，應聘用藥物管理、監製或技術人員者，其所聘人員之執業執照或證明文件。

二、藥商為公司組織者，其公司執照、公司組織章程影本。

三、藥物販賣業者，其營業地址、場所（貯存藥品倉庫）及主要設備之平面略圖。

四、藥物製造業者，其工廠登記證及其影本。

五、直轄市或縣（市）衛生主管機關所定之其他文件。

新設立公司組織之藥商，得由衛生主管機關先發給籌設許可文件，俟取得公司執照或工廠登記證後，再核發藥商許可執照。

第 11 條 申請藥商登記者，其藥商種類及應載明之營業項目，應依本法第十四條至第十八條之規定。

西藥販賣業者，由藥劑生駐店管理時，其營業項目應加註不販賣麻醉藥品。

藥商經營醫用放射性藥品者，應依有關法令規定，申請核准後始得販賣。

第 12 條 藥品製造業者依本法第十六條規定在其製造加工之同一處所經營自製產品之批發、輸出、自用原料輸入及兼營自製產品之零售業務者，得由其監製人兼為管理之。但兼營非本藥商產品之販賣業務或分設處所經營各該業務者，應分別聘管理人員，並辦理藥品販賣業之藥商登記。

藥品製造業者依本法第五十八條規定，委託他廠製造之產品，其批發、輸出及零售，得依前項前段規定辦理。

第 13 條 醫療器材製造業者依本法第三十二條規定應聘技術人員之醫療器材類別及其技術人員資格，依左列規定：

一、製造一般醫療設備、臨床檢驗設備及生物材料設備者，應聘國內公立或立案之私立專科以上學校或經教育部承認之國外專科以上學校理、工、醫、農等相關科、系、所畢業之專任技術人員駐廠監製。

二、製造隱形眼鏡鏡片消毒藥水（錠）、移植器官保存液、衛生材料、衛生棉條業者，應聘專任藥師駐廠監製。

第 14 條 藥商許可執照、藥局執照，應懸掛於營業處所之明顯位置。

第 15 條 本法第二十七條第一項所稱應辦理變更登記之事項，包括藥商登記事項之變更及自行停業、復業或歇業。

前項應辦理變更登記事項，藥商應自事實發生之日起十五日內，向原核准登記之衛生主管機關申請辦理變更登記。

第 16 條 藥商辦理變更登記，除遷址變更登記，應先向衛生主管機關申請辦理外，其他公司組織或商業登記事項之變更，應先向商業主管機關辦妥各該變更登記。

第 17 條 藥商依本法第二十八條或第二十九條規定聘用之管理或監製人員，或第三十一條、第三十二條規定聘用之技術人員，因解聘、辭聘或其他原因不能執行其任務而未另行聘置時，應即停止營業，並申請停業或歇業之登記。

第 18 條 藥品販賣業者依本法第二十八條規定聘用之藥師、藥劑生或中醫師，或本法第十九條規定親自主持藥局業務之藥師、藥劑生，均應親自在營業場所執行業務，其不在場時，應於門口懸掛明顯標示。

第 19 條 （刪除）

第 20 條 （刪除）

第 21 條 （刪除）

第 22 條 （刪除）

第 22-1 條 依本法第三十九條第二項規定申請輸入試製藥品原料藥者，應繳納費用，並填具申請書及檢附左列資料，送請中央衛生主管機關核辦：

一、藥商許可執照。

二、試製計畫書。

三、經濟部工廠登記證。但研發單位者，不在此限。

四、委託其他藥商辦理輸入試製藥品原料藥者，應檢附委託書及該藥商之藥商許可執照。

第 23 條 （刪除）

第 23-1 條 中央衛生主管機關對於藥物之查驗，得委託衛生財團法人或其他相關團體、機構辦理學術性研究、安全、臨床試驗等技術性資料之審查業務。

第 24 條 本法第三十九條、第四十條所稱藥物查驗登記事項如左：

一、藥物中文及外文品名。

二、藥品處方及藥品劑型。

三、醫療器材成分、材料、結構及規格。

四、藥物標籤、仿單及包裝。

五、藥品之直接包裝。

六、適應症、效能、性能、用法、用量及類別。

七、藥物製造方法、檢驗規格及檢驗方法。

八、藥商名稱。

九、製造廠廠名及廠址。

一○、其他經中央衛生主管機關指定登記事項。

第 25 條 （刪除）

第 26 條 （刪除）

第 27 條 國內製造之藥物，其標籤、仿單、包裝應以中文為主，所附外文文字應小於中文。

國外輸入之藥物，除應加附中文仿單外，其標籤、包裝均應另以中文載明品名、類別、許可證字號及輸入藥商名稱、地址，且應以中文或依習慣能

辦明之方式刊載有效期間或保存期限；其中文品名之文字不得小於外文。

第 28 條 藥商名稱之變更，涉及權利之移轉者，應由雙方共同提出申請。

第 29 條 （刪除）

第 30 條 （刪除）

第 31 條 輸出藥物為應輸出地區購買者之要求，須變更藥物名稱、標籤、仿單、包裝或附加外文者，應檢附其所變更之實樣各二份，申請中央衛生主管機關核定。

前項經變更名稱、標籤、仿單、包裝或附加外文之藥物，不得用於內銷。

第 32 條 （刪除）

第 33 條 本法第四十九條所稱不得買賣，包括不得將藥物供應非藥局、非藥商及非醫療機構。

第 34 條 依本法第五十三條第二項為輸入原料藥之分裝，應由輸入之藥商於符合優良藥品製造規範之藥廠分裝後，填具申請書，連同藥品許可證影本、海關核發之進口報單副本、原廠檢驗成績書、檢驗方法及其他指定文件，申請中央衛生主管機關備查。

經分裝之原料藥，以銷售藥品製造業者為限；所使用之標籤應分別刊載左列事項：

一、廠商名稱及地址。

二、品名及許可證字號。

三、效能或適應症。

四、批號。

五、分裝藥商名稱及地址。

六、分裝日期。

七、製造日期及有效期間或保存期限。

八、其他依規定應刊載事項。

前項第七款經中央衛生主管機關明令公告免刊載者，不在此限。

第 35 條 生物藥品之容器、標籤、仿單及包裝，除應依本法第七十五條規定刊載外，含有防腐劑者，應標明防腐劑含量。

第 36 條 依本法第七十四條所規定辦理之藥品檢驗封緘，其審查或檢驗結果為不合格者，國外輸入藥品應由直轄市或縣（市）衛生主管機關派員監督原輸入藥商限期退運；本國製造藥品可改製使用者，由直轄市或縣（市）衛生主管機關派員監督原製造廠商限期改製。屆期未能退運或改製，或不能改製者，應予以銷燬。

第 37 條 藥物有本法第八十條第一項第一款至第三款所列情形之一者，藥商、藥局及醫療機構，應自公告或依法認定之日起立即停止輸入、製造、批發、陳

列、調劑、零售，其製造或輸入之業者，並應於三個月內收回市售品，連同庫存品依本法第七十九條規定處理。

藥物有本法第八十條第一項第四款或第五款情形之一者，其製造或輸入之業者，應自藥物許可證到期或包裝、標籤、仿單經核准變更之日起六個月內收回市售品，連同庫存品送經直轄市或縣（市）衛生主管機關驗章後，始得販賣。

第 38 條 取締偽藥、劣藥、禁藥、不良醫療器材及未經許可製造或輸入之醫療器材，直轄市衛生主管機關得設置查緝中心；縣（市）衛生主管機關得設置查緝小組。

第 39 條 舉發偽藥、劣藥、禁藥、不良醫療器材或未經核准製造或輸入之醫療器材經緝獲者，應由直轄市或縣（市）衛生主管機關依左列標準計點核發獎金：

一、舉發製造或輸入偽藥、禁藥或未經核准製造或輸入醫療器材者：四至十點。

二、舉發以批發方式轉售（讓）偽藥、禁藥或未經核准製造或輸入醫療器材者：二至五點。

三、舉發零售、運送、儲（寄）藏、牙保或意圖販賣而陳列偽藥、禁藥或未經核准製造或輸入醫療器材者：二至三點。

四、舉發製造、輸入、販賣劣藥或不良醫療器材者：二至三點。

每點獎金之數額，由直轄市或縣（市）衛生主管機關視情況訂定，並編列預算支應之。中央衛生主管機關於必要時，得編列緝獲獎金補助之。

第 40 條 二人以上聯名舉發前條之案件，其獎金應由原舉發人聯名具領。二人以上分別舉發案件而有相同部分者，其獎金應發給最先舉發者；如無法分別先後時，平均分發之。

第 41 條 協助查緝機關緝獲偽藥、劣藥、禁藥、不良醫療器材及未經核准製造或輸入之醫療器材者，其獎勵準用關於舉發人之規定。

第 42 條 依本細則應發給獎金者，應由緝獲偽藥、劣藥、禁藥、不良醫療器材及未經核准製造或輸入醫療器材之機關敘明事實申請之。但同時符合本細則或其他法令規定給予獎勵者，不得重複給獎。

第 43 條 對於舉發人或協助緝獲偽藥、劣藥、禁藥、不良醫療器材及未經核准製造或輸入醫療器材者之姓名，應嚴予保密，不得洩漏。

第 44 條 登載或宣播藥物廣告，應由領有藥物許可證之藥商，填具申請書，連同藥物許可證影本、核定之標籤、仿單或包裝影本、廣告內容及審查費，申請中央或直轄市衛生主管機關核准後為之。

第 45 條 藥物廣告所用之文字圖畫，應以中央衛生主管機關所核定之藥物名稱、劑型、處方內容、用量、用法、效能、注意事項、包裝及廠商名稱、地址為

限。

中藥材之廣告所用文字，其效能應以本草綱目所載者為限。

第 46 條 藥物廣告應將廠商名稱、藥物許可證及廣告核准文件字號，一併登載或宣播。

第 47 條 藥物廣告之內容，具有左列情形之一者，應予刪除或不予核准：

一、涉及性方面之效能者。

二、利用容器包裝換獎或使用獎勵方法，有助長濫用藥物之虞者。

三、表示使用該藥物而治癒某種疾病或改進某方面體質及健康或捏造虛偽情事藉以宣揚藥物者。

四、誇張藥物效能及安全性者。

第 48 條 （刪除）

第 49 條 （刪除）

第 50 條 本法第一百零二條第二項所稱醫療急迫情形，係指醫師於醫療機構為急迫醫療處置，須立即使用藥品之情況。

第 51 條 （刪除）

第 52 條 （刪除）

第 53 條 本法及本細則所定文書格式，由中央衛生主管機關定之。

第 54 條 本細則自發布日施行。

二、美國學名藥重要法規

(一) Hatch-Waxman Law

略。

請洽：政大智財所。

(二) CREATE Act

An Act

To amend title 35, United States Code, to promote cooperative research involving universities, the public sector, and private enterprises.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ‘‘Cooperative Research and Technology Enhancement (CREATE) Act of 2004’’.

SEC. 2. COLLABORATIVE EFFORTS ON CLAIMED INVENTIONS.

Section 103(c) of title 35, United States Code, is amended to read as follows:

‘‘(c)(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f),and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

(2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if—

(A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

(B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement;

And

(C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(3) For purposes of paragraph (2), the term 'joint research agreement' means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.''.

SEC. 3. EFFECTIVE DATE.

(a) IN GENERAL.—The amendments made by this Act shall apply to any patent granted on or after the date of the enactment of this Act.

(b) SPECIAL RULE.—The amendments made by this Act shall not affect any final decision of a court or the United States Patent 35 USC 103 note.

Cooperative Research and Technology Enhancement (CREATE) Act of 2004.35 USC 1 note.Dec. 10, 2004 [S. 2192]

PUBLIC LAW 108–453—DEC. 10, 2004 118 STAT. 3597

LEGISLATIVE HISTORY—S. 2192 (H.R. 2391):

HOUSE REPORTS: No. 108–425 accompanying H.R. 2391 (Comm. on the Judiciary).

CONGRESSIONAL RECORD, Vol. 150 (2004):

June 25, considered and passed Senate.

Nov. 20, considered and passed House.

A

and Trademark Office rendered before the date of the enactment of this Act, and shall not affect the right of any party in any action pending before the United States Patent and Trademark Office or a court on the date of the enactment of this Act to have that party's rights determined on the basis of the provisions of title 35, United States Code, in effect on the day before the date of the enactment of this Act.

三、美國案例原文

(一) SCHERING-PLOUGH CORP. v. FTC 案例原文

FAY, Circuit Judge:

Pharmaceutical companies Schering-Plough Corp. and Upsher-Smith Laboratories, Inc. petition for review of an order of the Federal Trade Commission ("FTC") that they cease and desist from being parties to any agreement settling a patent infringement lawsuit, in which a generic manufacturer either (1) receives anything of value; and (2) agrees to suspend research, development, manufacture, marketing, or sales of its product for any period of time. The issue is whether substantial evidence supports the conclusion that the Schering-Plough settlements unreasonably restrain trade in violation of Section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and Section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45(c). We have jurisdiction pursuant to 15 U.S.C. § 45(c), and, for the reasons discussed below, we grant the petition for review and set aside and vacate the FTC's order.

I. Factual Background

A. The Upsher Settlement

Schering-Plough ("Schering") is a pharmaceutical corporation that develops, markets, and sells a variety of science-based medicines, including antihistamines, corticosteroids, antibiotics, anti-infectives and antiviral products. Schering manufactures and markets an extended-release microencapsulated potassium chloride

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

FILED
U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
March 8, 2005
THOMAS K. KAHN
CLERK

No. 04-10688

Agency No. FTC 9297

SCHERING-PLOUGH CORPORATION,
UPSHER-SMITH LABORATORIES, INC.,
a Minnesota corporation having its
principal place of business in Minnesota,

Petitioners,

versus

FEDERAL TRADE COMMISSION,

Respondent.

Petitions for Review of a Decision of the
Federal Trade Commission

(March 8, 2005)

Before DUBINA and FAY, Circuit Judges, and GOLDBERG*, Judge.

* Honorable Richard W. Goldberg, Judge, United States Court of International Trade, sitting by designation.

product, K-Dur 20,which is a supplement generally taken in conjunction with prescription medicines for the treatment of high blood pressure or congestive heart disease. The active ingredient in K-Dur 20, potassium chloride, is commonly used and unpatentable. Schering, however, owns a formulation patent on the extended-release coating, which surrounds the potassium chloride in K-Dur 20, patent number 4,863,743 (the "'743 patent"). The '743 patent expires on September 5, 2006.[1]

In late 1995, Upsher-Smith Laboratories ("Upsher"), one of Schering's competitors, sought Food and Drug Administration ("FDA") approval to market Klor Con M20 ("Klor Con"), a generic version of K-Dur 20.[2] Asserting that Upsher's

[1] Schering also markets another version of this product, K-Dur 10, the coating of which is also covered by the '743 patent. The difference between the two is dosage: K-Dur 20 contains twice as much potassium as K-Dur 10. This lawsuit only involves K-Dur 20.

The '743 patent claims a pharmaceutical dosage unit in tablet form for oral administration of potassium chloride. The tablet contains potassium chloride crystals coated with a cellulose-type material. The novel feature in the '743 patent is the viscous coating, which is applied to potassium chloride crystals. The coating provides a sustained-release delivery of the potassium chloride.

[2] The FDA must approve any new drug before it can be marketed or sold in the United States. Previously, applications for FDA approval proceeded under a new drug application ("NDA"). 21 U.S.C. § 355(b). This cumbersome and involved process required each applicant to submit safety and efficacy studies, even if it duplicated previous studies done on identical drugs with the same ingredients. In 1984, Congress passed Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984). The purpose of the Hatch-Waxman Act was threefold: (1) to reduce the average price paid by consumers; (2) preserve the technologies pioneered by the brand-name pharmaceutical companies; and (3) create an abbreviated new drug application ("ANDA") to bring generic drugs to the market.

The ANDA process allows the manufacturers of generic drugs to gain early entry into the market. Hatch-Waxman's truncated procedure avoids the duplication of expensive safety and efficacy studies, so long as the generic manufacturer proves that its drug is bio-equivalent to the

product was an infringing generic substitute, Schering sued for patent infringement. K-Dur 20 itself was the most frequently prescribed potassium supplement, and generic manufacturers such as Upsher could develop their own potassium-chloride supplement as long as the supplement's coating did not infringe on Schering's patent.

In 1997, prior to trial, Schering and Upsher entered settlement discussions. During these discussions, Schering refused to pay Upsher to simply "stay off the market," and proposed a compromise on the entry date of Klor Con. Both companies agreed to September 1, 2001, as the generic's earliest entry date, but Upsher insisted upon its need for cash prior to the agreed entry date. Although still opposed to paying Upsher for holding Klor Con's release date, Schering agreed to a separate deal to license other Upsher products. Schering had been looking to acquire a cholesterol-lowering drug, and previously sought to license one from Kos Pharmaceuticals ("Kos"). After reviewing a number of Upsher's products, Schering became particularly interested in Niacor-SR ("Niacor"), which was a sustained-release niacin

already-approved brand-name/pioneer drug. As part of the application process, the generic applicant must certify that the relevant patent(s) on the brand-name drug are either invalid or will not be infringed. This is commonly known as a "Paragraph IV certification." The patent holder is then notified of the ANDA, and if the patent holder sues for infringement within forty-five days of receiving the notice, the FDA automatically institutes a thirty-month delay on the generic manufacturer's ANDA approval. See 21 U.S.C. 355(j)(5)(B)(iii).

As part of its ANDA, Upsher certified that Schering's patent was either invalid or that Upsher did not infringe on that patent. When Schering brought suit, the thirty-month delay was activated.

product used to reduce cholesterol.[3]

Upsher offered to sell Schering an exclusive license to market Niacor worldwide, except for North America. The parties executed a confidentiality agreement in June 1997, and Schering received licenses to market five Upsher products, including Niacor. In relation to Niacor, Schering received a data package, containing the results of Niacor's clinical studies. The cardiovascular products unit of Schering's Global Marketing division, headed by James Audibert ("Audibert") evaluated Niacor's profitability and effectiveness.

According to the National Institute of Health, niacin was the only product known to have a positive effect on the four lipids related to cholesterol management. Immediate-release niacin, however, created an annoying - but innocuous - side effect of "flushing," which reduced patient compliance. On the other hand, previous versions of sustained-release niacin supplements, like Niacor, had been associated with substantial elevations in liver enzyme levels.

Schering knew of the effects associated with niacin supplements, but continued with its studies of Niacor because it had passed the FDA's medical review

[3] Schering's focus on Niacor is consistent with its previous attempt to purchase the rights to Niaspan, another sustained-release niacin product, which Kos was in the process of developing during this time. Negotiations between Kos and Schering broke down several months before Upsher offered Niacor to Schering.

and determined that it would likely be approved. More important, the clinical trials studied by Audibert demonstrated that Niacor reduced the flushing effect to one-fourth of the immediate-release niacin levels and only increased liver enzymes by four percent, which was generally consistent with other cholesterol inhibitors. Based on this data, Audibert constructed a sales and profitability forecast, and concluded that Niacor's net present value at that time would be between $245-265 million.

On June 17, 1997, the day before the patent trial was scheduled to begin, Schering and Upsher concluded the settlement. The companies negotiated a three-part license deal, which called for Schering to pay (1) $60 million in initial royalty fees; (2) $10 million in milestone royalty payments; and (3) 10% or 15% royalties on sales. Schering's board approved of the licensing transaction after determining the deal was valuable to Schering. This estimation corresponds to the independent valuation that Schering completed in relation to Kos' Niaspan, a substantially similar product to Niacor. That evaluation fixed Niaspan's net present value between $225-265 million.

The sales projections for both the Kos and Upsher products are substantially similar. Raymond Russo ("Russo") estimated Niaspan (Kos' supplement) sales to reach $174 million by 2005 for the U.S. market. Comparably, and more conseratively, Audibert predicted Niacor (Upsher's supplement) to reach $136 million for the global market outside the United States, Canada, and Mexico, which is either equal to or

larger than U.S. market alone.[4]

After acquiring the licensing rights to Niacor, Schering began to ready its documents for overseas filings. In late 1997, however, Kos released its first-quarter sales results for Niaspan, which indicated a poor performance and lagging sales. Following this announcement, Kos' stock price dramatically dropped from $30.94 to $16.56, and eventually bottomed out at less than $6.00. In 1998, with Niaspan's disappointing decline as a precursor, Upsher and Schering decided further investment in Niacor would be unwise.

B. The ESI Settlement

In 1995, ESI Lederle, Inc. ("ESI"), another pharmaceutical manufacturer, sought FDA approval to market its own generic version of K-Dur 20 called "Micro-K 20."[5] Schering sued ESI in United States District Court, and, as part of the pretrial process, the trial judge prompted the parties to engage a court-supervised mediation, pursuant to the Civil Justice Reform Act, 28 U.S.C. § 471 et seq. (1991). The trial court appointed U.S. Magistrate Judge Thomas Rueter ("Judge Rueter") to mediate

[4] Indeed, there is the indication of some internal independence between Schering's evaluation of Niaspan and Niacor, as two different teams examined the products and arrived at similar estimates.

[5] On December 22, 1995, ESI submitted an ANDA to the FDA that reference K-Dur 20 and contained a Paragraph IV certification to Schering's '743 patent. On December 29, 1995, ESI notified Schering of this certification containing data from a study demonstrating Micro-K 20's bioequivalency to Schering's K-Dur 20's tablets.

the fifteen-month process, which resulted in nothing more than an impasse.

Finally, in December 1997, Schering offered to divide the remaining patent life with ESI and allow Micro-K 20 to enter the market on January 1, 2004 - almost three years ahead of the patent's September 2006 expiration date.[6] ESI accepted this offer, but demanded on receiving some form of payment to settle the case. At Judge Rueter's suggestion, Schering offered to pay ESI $5 million, which was attributed to legal fees, however, ESI insisted upon another $10 million. Judge Rueter and Schering then devised an amicable settlement whereby Schering would pay ESI up to $ 10 million if ESI received FDA approval by a certain date. Schering doubted the likelihood of this contingency happening, and Judge Rueter intimated that if Schering's prediction proved true, it would not have to pay the $10 million.[7] The settlement was signed in Judge Rueter's presence on January 23, 1998.[8]

[6] There was also a side agreement in this settlement that provided for a payment of $15 million in return for the right to license generic enalpril and buspirone from ESI..

[7] ESI provided Schering with information related to the Micro-K 20's current approval status. The summary noted the difficulties ESI had up to that point in trying to obtain FDA approval for its proposed generic version. The primary concern was ESI's bioequivalence study, which had been performed in 1989. The FDA found five different deficiencies with regard to that study, and ESI did not respond to those deficiencies until May 1997. ESI then began a new bioequivalence study in December 1997.

[8] Under the final settlement agreement, dated June 19, 1998, Schering agreed to pay ESI a $5 million noncontingent payment, representing legal fees, and an additional $10 million contingent on ESI's FDA approval. Schering and ESI also entered into a contemporaneous license agreement whereby ESI granted Schering the licenses to enalpril and buspirone in exchange for $15 million.

C. The FTC Complaint

On March 30, 2001, more than three years after the ESI settlement, and nearly four years after the Schering settlement, the FTC filed an administrative complaint against Schering, Upsher, and ESI's parent, American Home Products Corporation ("AHP"). The complaint alleged that Schering's settlements with Upsher and ESI were illegal agreements in restraint of trade, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The complaint also charged that Schering monopolized and conspired to monopolize the potassium supplement market.[9]

II. Procedural History

The Complaint was tried before an Administrative Law Judge (ALJ) from January 23, 2002 to March 28, 2002. Numerous exhibits were admitted in evidence, and the ALJ heard testimony from an array of expert witnesses presented by both sides. In his initial decision, the ALJ found that both agreements were lawful settlements of legitimate patent lawsuits, and dismissed the complaint. Specifically, the ALJ ruled that the theories advanced by the FTC, namely, that the agreements

[9] On October 12, 2001, the Complaint against AHP was withdrawn to consider a proposed consent agreement. The FTC approved a final consent order on April 2, 2002. AHP was not a party to either the trial before the ALJ or any subsequent proceedings, and is not a party to this appeal. The legality of the Schering's settlement with ESI/AHP, however, remained at issue with respect to Schering.

were anticompetitive, required either a presumption of (1) that Schering's '743 patent was invalid; or (2) that Upsher's or ESI's generic products did not infringe the '743 patent. The ALJ concluded that such presumptions had no basis in law or fact. Moreover, the ALJ noted that Schering's witnesses went unrebutted by FTC complaint counsel, and credibly established that the licensing agreement with Upsher was a "bona-fide arm's length transaction."

The ALJ further found that the presence of payments did not make the settlement anticompetitive, per se. Rather, the strength of the patent itself and its exclusionary power needed to be assessed. The initial decision highlighted the FTC's failure to prove that, absent a payment, either better settlement agreements or litigation results would have effected an earlier entry date for the generics. Finally, the ALJ found no proof that Schering maintained an illegal monopoly within the relevant potassium chloride supplement market.

The FTC's complaint counsel appealed this decision to the full Commission. On December 8, 2003, the Commission issued its opinion, reversing the ALJ's initial decision, and agreeing with complaint counsel that Schering's settlements with ESI and Upsher had violated the FTC Act and the Sherman Act. Although it refrained from ruling that Schering's payments to Upsher and ESI made the settlements per se illegal, the Commission concluded that the quid pro quo for the payment was an

agreement to defer the entry dates, and that such delay would injure competition and consumers.

In contrast to the ALJ's inquiry into the merits of the '743 patent litigation, the Commission turned instead to the entry dates that "might have been" agreed upon in the absence of payments as the determinative factor. Despite the Commission's assumption that the parties could have achieved earlier entry dates via litigation or non-monetary compromises, it also acknowledged that the settled entry dates were non-negotiable. Upon review of the settlement payments, the Commission determined that neither the $60 million to Upsher nor the $30 million to ESI represented legitimate consideration for the licenses granted by Upsher or ESI's ability to secure FDA approval of its generic.[10] Consequently, the Commission prohibited settlements under which the generic receives anything of value and agrees to defer its own research, development, production or sales activities. Nevertheless, the Commission carved out one arbitrary exception for payments to the generic: beyond a "simple compromise" to the entry date, if payments can be linked to litigation costs (not to exceed $2 million), and the Commission is notified of the settlement, then the parties

[10] The contradictory nature of the Commission's opinion is exemplified by its assessment of the ESI settlement. Although the Commission found the payment to be unjustified and in violation of the law, it simultaneously explained that "[a]s a matter of prosecutorial discretion, we might not have brought a stand-alone case based on such relatively limited evidence."

need not worry about a later antitrust attack. Neither of the Schering agreements fit this caveat, and Schering and Upsher timely petition for review.

III. Standard of Review

We review the FTC's findings of fact and economic conclusions under the substantial evidence standard. 15 U.S.C. § 45(c); see Orkin Exterminating Co., Inc. v. FTC, 849 F.2d 1354 (11th Cir. 1988); Olin Corp. v. FTC, 986 F.2d 1295 (9th Cir. 1993). The FTC's findings of fact, "if supported by evidence, shall be conclusive." 15 U.S.C. § 45(c). This standard applies regardless whether the FTC agrees with the ALJ. Thiret v. FTC, 512 F.2d 176, 179 (10th Cir. 1975). We may, however, examine the FTC's findings more closely where they differ from those of the ALJ. Id.; California Dental Association v. FTC, 128 F.3d 720, 725 (9th Cir. 1997), rev'd on other grounds, 526 U.S. 756 (1990); see also ITT Continental Baking Co. v. FTC, 532 F.2d 207, 219 (2d Cir. 1976); American Cyanamid Co. v. FTC, 363 F.2d 757, 772-73 (6th Cir. 1966). "Substantial evidence is more than a mere scintilla," and we require "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229, 83 L. Ed. 126, 59 S. Ct. 206 (1938); Consolo v. Federal Maritime Commission, 383 U.S. 607, 620, 86 S.Ct. 1018, 1026, 16 L.Ed.2d 131 (1966); see NLRB v. Gimrock Constr., Inc., 247 F.3d 1307, 1309 (11th Cir. 2001).While we afford the FTC some deference as to its

informed judgment that a particular commercial practice violates the FTC Act, we review issues of law de novo. See FTC v. Indiana Federation of Dentists, 476 U.S. 447, 454, 106 S.Ct. 2009, 2015-16, 90 L.Ed.2d 445 (1986).

In their arguments, the parties urge that Universal Camera provides the yardstick by which to measure the evidence at issue. Indeed, in 1951, the Supreme Court clarified the substantial evidence standard for reviewing an administrative agency's decision. Universal Camera Corp. v. NLRB, 340 U.S. 474, 487-88, 95 L. Ed. 456, 71 S. Ct. 456 (1951). In Universal Camera, the ALJ found an employee was lawfully discharged for insubordination rather than his appearance at an NLRB proceeding. The factual testimony directly conflicted, and the ALJ's finding clearly relied on a credibility determination. The Board reversed the holding. On judicial review, the court of appeals hesitated to consider the ALJ's initial ruling because the Administrative Procedure Act gave the Board "all the powers it would have had in making the initial decision." 5 U.S.C. § 557(b). Thus, the Second Circuit affirmed the Board's decision. The Supreme Court disagreed, and held that the plain language of the statute required a review of the record as a whole, which included the ALJ's decision. Universal Camera, 340 U.S. at 493.

Although Universal Camera involved the NLRB, and not the FTC, the results are applicable here. When we review a jury verdict, we ignore all evidence contrary

to the verdict and then draw every reasonable inference in favor of the verdict from the remaining evidence. In the administrative setting, however, Universal Camera dictates that "the substantiality of the evidence must take into account whatever in the record fairly detracts from its weight." Id. at 488. We are mindful that we do not review the record to draw our own conclusions that we then measure against an administrative agency; rather, we must consider all of the evidence when drawing our conclusions about the reasonableness of an agency's findings of fact. The evidence must be such that it would be possible for a reviewing court to reach the same conclusions that the administrative fact-finder did. If this condition is not met, then the substantial evidence test requires that the administrative decision be reversed. Id.

IV. Discussion

The question remains whether the Commission's conclusions are legally sufficient to establish a violation of the Sherman Act and the FTC Act--that is, whether Schering's agreements with Upsher and ESI amount to an "unreasonable" restraint of trade. In Valley Drug, this Court stated that the "ultimate purpose of the antitrust inquiry is to form a judgment with respect to the competitive significance of the restraint at issue." Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1303-04 (11th Cir. 2003) (citing NCAA v. Bd. of Regents Okla. Univ., 468 U.S. 85, 103, 104 S.Ct. 2948, 2962, 82 L.Ed.2d 70 (1984)). We wrote that the focus of antitrust

analysis should be on "what conclusions regarding the competitive impact of a challenged restraint can confidently be drawn from the facts demonstrated by the parties." Valley Drug, 344 F.3d at 1304.

Valley Drug involved an interim settlement agreement between a patent-holding pharmaceutical company and its potential generic competitor. Under the agreement, the patent holder paid the generic manufacturer $4.5 million per month to keep its product off the market until resolution of the underlying patent infringement suit. The lower court determined that the payments amounted to a per se violation of antitrust laws. See In re Terazosin Hydrochloride Antitrust Litig., 164 F.Supp.2d 1340 (S.D. Fla. 2000). We reversed that decision, and concluded that monetary payments made to an alleged infringer as part of a patent litigation settlement did not constitute a per se violation of antitrust law. Valley Drug, 344 F.3d at 1309.

Although we acknowledged in Valley Drug that an agreement to allocate markets is "clearly anticompetitive," resulting in reduced competition, increased prices, and a diminished output, we nonetheless reversed for a rather simple reason: one of the parties owned a patent. Id. at 1304. We recognized the effect of agreements that employ extortion-type tactics to keep competitors from entering the market. In the context of patent litigation, however, the anticompetitive effect may be no more

broad than the patent's own exclusionary power. To expose those agreements to antitrust liability would "obviously chill such settlements." Id. at 1309.

Both the ALJ and the Commission analyzed the Schering agreements according to the rule of reason analysis, albeit under two different methodologies. To the contrary, the district court in Valley Drug approached the agreements in that case from the perspective of whether they were a per se violation of antitrust laws. Under the Supreme Court's guidance, an alleged restraint may be found unreasonable either because it fits within a category of restraints that has been held to be "per se" unreasonable, or because it violates the so-called "Rule of Reason."[11] The rule of reason tests "'whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.'" FTC v. Indiana Federation of Dentists, 476 U.S. 447, 457, 106 S.Ct. 2009, 2017, 90 L.Ed.2d 445 (1986) (quoting Chicago Board of Trade v. United States, 246 U.S. 231, 238, 385 S.Ct. 232, 244 (1918)).[12]

[11] The majority of antitrust claims are analyzed under the rule of reason. State Oil Co. v. Kahn, 522 U.S. 3, 20 (1997). Courts generally determine the reasonableness of a particular agreeement by reference to the surrounding facts and circumstances under the rule of reason. Generally, a per se analysis is applied only in limited circumstances, and after experience and pattern establish that a particular class of restraint is manifestly anticompetitive. Broadcast Music, Inc. v. Columbia Broad. Sys., Inc. U.S. 1, 9 (1979). Essentially, the per se rule should only be employed when the conduct has "pernicious effect on competition" and "lack[s]...any redeeming virtue." Continental T.V. Inc. v. GTE Sylvania Inc., 433 U.S. 36, 50 (1977).

[12] By and large, the construction of the rule of reason inquiry has remained unaltered since the Supreme Court first articulated it in Chicago Board of Trade v. United States, 246 U.S.

Both the ALJ's initial decision and the Commission's opinion rejected the *per se* approach, and instead employed the rule of reason. The traditional rule of reason analysis requires the factfinder to "weigh all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition." Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49, 97 S.Ct. 2549, 2557, 53 L.Ed.2d 568 (1977). The plaintiff bears an initial burden of demonstrating that the alleged agreement produced adverse, anti-competitive effects within the relevant product and geographic markets, i.e., market power. See FTC v. Indiana Federation of Dentists, 476 U.S. 447, 460-61, 106 S.Ct. 2009, 2019, 90 L.Ed.2d 445 (1986).[13]

Once the plaintiff meets the burden of producing sufficient evidence of market power, the burden then shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective. A restraint on competition cannot be justified solely on the basis of social welfare concerns. See, e.g., National Society of Professional Engineers v. United States, 435 U.S. 679, 98 S.Ct. 1355, 55 L.Ed.2d 637 (1978) ; Indiana Dentists, 476 U.S. at 463, 106 S.Ct. at 2020. In rebuttal then, the plaintiff must demonstrate that the restraint is not reasonably necessary to achieve the stated objective. Bhan v. NME Hospitals, Inc., 929 F.2d 1404, 1413 (9th Cir.), cert. denied, 502 U.S. 994, 112 S.Ct. 617, 116 L.Ed.2d 639 (1991).

In the present case, the Commission emphasized that its rule of reason standard required a methodology different from that set out by the ALJ's initial decision. The Commission chided the ALJ's approach - which evaluated the strength of the patent, defined the relevant geographic and product markets, calculated market shares, and then drew inferences from the shares and other industry characteristics - as an inappropriate manner of analyzing the competitive effects of the parties' activities. Instead, the Commission's rule of reason dictated application of the Indiana Federation exception, in that complaint counsel need not prove the relevant market. See 476 U.S. 460-61. Rather, the FTC was only required to show a detrimental market effect. Thus, under the Commission's standard, once the FTC met the low threshold of demonstrating the anticompetitive nature of the agreements, it found that Schering and Upsher did not sufficiently establish that the challenged activities were

231, 238, 38 S.Ct. 242, 244, 62 L.Ed. 683 (1918):

> [T]he court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts.

[13] Indiana Dentists noted an exception to the burden of proving market power: "Since the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, 'proof of actual detrimental effects, such as a reduction of output,' can obviate the need for an inquiry into market power, which is but a 'surrogate for detrimental effects.'" 476 U.S. at 460-61 7 (citing P. Areeda, Antitrust Law ¶ 1511, p. 429 (1986)).

justified by procompetitive benefits. Despite the appearance that it openly considered Schering and Upsher's procompetitive affirmative defense, the Commission immediately condemned the settlements because of their absolute anti-competitive nature, and discounted the merits of the patent litigation. It would seem as though the Commission clearly made its decision before it considered any contrary conclusion.

We think that neither the rule of reason nor the *per se* analysis is appropriate in this context. We are bound by our decision in Valley Drug where we held both approaches to be ill-suited for an antitrust analysis of patent cases because they seek to determine whether the challenged conduct had an anticompetitive effect on the market. 344 F.3d 1294, 1311 n.27.[14] By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present. "What is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the

[14] On remand, the district court in Valley Drug still applied a per se analysis, and found those agreements to be illegal. See In re Terazosin Hydrochloride Antitrust Litigation, __ F.Supp.2d __ (S.D. Fla. 2005).We note that the case at bar is wholly different from Valley Drug. The critical difference is that the agreements at issue in Valley Drug did not involve final settlements of patent litigation, and, moreover, the Valley Drug agreements did not permit the generic company to market its product before patent expiration. On remand, the district court emphasized that the "[a]greement did not resolve or even simplify Abbott's patent infringement action... to the contrary, the Agreement tended to prolong that dispute to Abbott's advantage, delaying generic entry for a longer period of time than the patent or any reasonable interpretation of the patent's protections would have provided." In re Terazosin Hydrochloride Antitrust Litigation, __ F.Supp.2d __ (S.D. Fla. 2005). Given these material distinctions, the same analysis cannot apply.

extent to which the patent laws prevent antitrust liability for such exclusionary effects." Id. Therefore, in line with Valley Drug, we think the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects. Valley Drug, 344 F.3d at 1312.[15]

A. The '743 Patent

"A patent shall be presumed valid." 35 U.S.C. § 282. See e.g., Doddridge v. Thompson, 22 U.S. 469, 483 (1824) (holding that a patent is presumed valid until the contrary is shown); Sure Plus Mfg. Co. v. Kobrin, 719 F.2d 1114, 1117 (11th Cir. 1983) ("Congress recognized the expertise of the patent office on this matter when it provided for a legal presumption in favor of patent validity for any patent issued by the patent office."). Engrafted into patent law is the notion that a patent grant bestows the right to exclude others from profiting by the patented invention." Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980); see Valley Drug, 344 F.3d at

[15] The Commission wrote that it would neither address the exclusionary power of Schering's patent nor compare the patent's scope to the exclusionary effect of the settlements. Rather, the Commission grounds its decision in the untenable supposition that without a payment there would have been different settlements with both ESI and Schering, resulting in earlier entry dates: "we cannot assume that Schering had a right to exclude Upsher's generic competition for the life of the patent any more than we can assume that Upsher had the right to enter earlier. In fact we make neither assumption, but focus on the effect that Schering's payment had to Upsher was likely to have on the generic entry date which the parties would otherwise have agreed to in a settlement."

1304 ("A patent grants its owner the lawful right to exclude others."). Thus, the Patent Act essentially provides the patent owner "with what amounts to a permissible monopoly over the patented work." Telecom Technical Services Inc. v. Rolm Co., 388 F.3d 820, 828 (11th Cir. 2004) (citing Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 135, 89 S.Ct. 1562, 23 L.Ed.2d 129 (1969)). The Patent Act also explicitly allows for the assignability of a patent; providing the owner with a right to "grant or convey an exclusive right under his application for patent...to the whole or any specified part of the United States." 35 U.S.C. § 261.

By virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products, Klor-Con and Micro-K 20, respectively, did not infringe Schering's patent. Although the exclusionary power of a patent may seem incongruous with the goals of antitrust law, a delicate balance must be drawn between the two regulatory schemes. Indeed, application of antitrust law to markets affected by the exclusionary statutes set forth in patent law cannot discount the rights of the patent holder. Simpson v. Union Oil Co., 377 U.S. 13, 14, 84 S.Ct. 1051, 12 L.Ed.2d 98 (1964). (Patent laws "are in pari materia with the antitrust laws and modify them pro tanto (as far as the patent laws go)."). Therefore, a patent holder does not incur antitrust liability when it chooses to exclude others from producing its patented work.

Valley Drug, 344 F.3d at 1305.

A patent gives its owner the right to grant licenses, if it so chooses, or it may ride its wave alone until the patent expires. Ethyl Gasoline Corp. v. United States, 309 U.S. 436, 456 (1940). What patent law does not do, however, is extend the patentee's monopoly beyond its statutory right to exclude. Mallinckrodt, Inc. v. Medipart, Inc. 976 F.2d 700, 708 (Fed. Cir. 1992); see also, United States v. Singer Mfg. Co., 374 U.S. 174, 196-197, 83 S.Ct. 1773, 10 L.Ed.2d 823 (1963) ("[B]eyond the limited monopoly which is granted, the arrangements by which the patent is utilized are subject to the general law.... [T]he possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly."). If the challenged activity simply serves as a device to circumvent antitrust law, then that activity is susceptible to an antitrust suit. Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc., 289 F.Supp.2d 986, 991 (N.D. Ill. 2003), In Asahi, Judge Posner gave an illustrative example of when certain conduct transcends the confines of the patent:

> Suppose a seller obtains a patent that it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices--masks--for fixing prices, in violation of antitrust law.

Id.

It is uncontested that potassium chloride is the unpatentable active ingredient in Schering's brand-name drug K-Dur 20. Schering won FDA approval in 1986 to sell its K-Dur 20 tablets. Under the Hatch-Waxman scheme, in order for Upsher and ESI to obtain FDA approval to market their generic versions of an approved drug product like K-Dur 20, they simply needed to demonstrate that the drugs were bioquivalent, i.e., that the "active ingredient of the new drug is the same as that of the listed drug." 21 U.S.C. § 355(j)(2)(A)(ii)(I).[16] K-Dur 20's uniqueness, and hence the reason for a patent, is the time-release capsule that surrounds the potassium chloride. Because the patent only covers the individualized delivery method (the sustained-release formula), and not the active ingredient itself, it is termed a "formulation" patent.

No one disputes that the '743 patent gave Schering the lawful right to exclude infringing products from the market until September 5, 2006. Nor is there any dispute that Schering's agreement with Upsher gave it a license under the '743 patent to sell a microencapsulated form of potassium chloride more than five years before the expiration of the '743 patent.[17] Likewise, ESI gained a license under the '743 patent to sell its microencapsulated version more than two years before the '743

[16] In fact, Upsher received final FDA approval to market its Klor-Con generic version in November 1998. ESI followed suit, gaining FDA approval for Micro-K 20 in June 1999.

[17] Upsher began selling Klor Con M20 on September 1, 2001.

patent expired. Perhaps most important, and which the ALJ duly noted, is that FTC complaint counsel acknowledged that it could not prove that Upsher and ESI could have entered the market on their own prior to the '743 patent's expiration on September 5, 2006. This reinforces the validity and strength of the patent.

Although the FTC alleges that Schering's settlement agreements are veiled attempts to disguise a quid pro quo arrangement aimed at preserving Schering's monopoly in the potassium chloride supplement market, there has been no allegation that the '743 patent itself is invalid or that the resulting infringement suits against Upsher and ESI were "shams." Additionally, without any evidence to the contrary, there is a presumption that the '743 patent is a valid one, which gives Schering the ability to exclude those who infringe on its product. Therefore, the proper analysis now turns to whether there is substantial evidence to support the Commission's conclusion that the challenged agreements restrict competition beyond the exclusionary effects of the '743 patent. Valley Drug, 344 F.3d at 1306; see also In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F.Supp. 2d 188, 196 (E.D.N.Y. 2003).[18]

[18] It is patently obvious that the Commission's opinion did not employ this analysis; preferring, instead, to proceed through its laborious rule of reason framework, eventually branding the challenged restraints to be illegal horizontal market allocation agreements. The Commission was ostensibly silent with regard to the '743 patent, yet it cavalierly dismissed our holding in Valley Drug, stating that a determination on the merits of the underlying patent disputes was "not supported by law or logic."

B. The Scope of Schering's Agreements

1. The Upsher Settlement

The FTC's complaint characterized the agreements at the center of this contest as "horizontal market allocation agreements," whereby Schering reserved its sales of K-Dur 20 for several years, while Upsher and ESI refrained from selling their generic versions of K-Dur 20 during that same time period. Adding to the FTC's ire is the presence of "reverse payments," represented by settlement payments from the patent owner to the alleged infringer. The Commission ruled that the coupling of reverse payments with an agreement by the generics not to enter the market before a particular date, "raise[d] a red flag that distinguishes this particular litigation settlement from most other patent settlements, and mandates a further inquiry." Slip. Op. at 29.

In the context of Schering's settlement with Upsher, the FTC argues that the $60 million payment from Schering to Upsher was not a bona fide royalty payment under the licenses Schering obtained for Niacor and five other Upsher products. Instead, according to the FTC, the royalty payments constituted payoffs to delay the introduction of Upsher's generic. The FTC concedes that its position fails if it cannot prove a direct causal link between the payments and the delay.

The trial before the ALJ covered 8,629 pages of transcript, involved forty-one

witnesses, and included thousands of exhibits. The trial revealed that Schering personnel evaluated Niacor, and forecast its profit stream with a net present value of $225-265 million. Upsher itself had invested significant time and financial resources in Niacor. Moreover, Schering had a long-documented and ongoing interest in licensing an extended-release niacin product, as evidenced by its efforts to acquire Niaspan from Kos Pharmaceuticals.

Evidence at trial also demonstrated that the personnel who evaluated Niaspan's potential were unaware of the ongoing litigation between Upsher and Schering, and had little, if any, incentive to inflate Niacor's value. Indeed, many of the estimates in conjunction with the Niacor evaluation traced the independent conclusions of the team that evaluated Niaspan. Schering's witnesses corroborated the documentary evidence, and the ALJ found the $60 million payment to Upsher to be a bona fide fair-value payment.

The Commission chose to align its opinion with the two witnesses presented by the FTC. One witness, Dr. Nelson Levy ("Levy") was proffered as an expert in pharmaceutical licensing and valuation. He concluded that the $60 million payment was "grossly excessive," and that Schering's due diligence in evaluating Niacor fell astonishingly short of industry standards. Levy cited Upsher and Schering's post-settlement behavior, as proof of the agreement's artificial nature. We are troubled by

Levy's testimony. Interestingly, Levy arrived at his conclusions without performing a quantitative analysis of Niacor or any of the other Upsher products licensed by Schering. Additionally, Levy lacked expertise in the area of cholesterol-lowering drugs and niacin supplements. Finally, Levy's unpersuasive appraisal of the post-settlement behavior blatantly ignored the parties' ongoing communications and the fact that the niacin market essentially bottomed out. Although the Commission's opinion does not state that it in relying on Levy's testimony, it curiously mirrors each of Levy's conclusions.

The FTC also offered Professor Timothy Bresnahan ("Bresnahan") to prove that Schering's payment was not for the Niacor license. While Bresnahan neither challenged Niacor's sales projections nor discounted its economic value, Bresnahan nonetheless opined that the payment was for Upsher's delayed entry, and not Niacor. Bresnahan based his conclusions on his interpretation of the parties' subjective incentives to trade a payment for delay. Bresnahan specifically pointed to Schering's failed transactions with Kos and the lack of other competitors vying for Niacor as evidence that the payment was not connected to the license.

Like the Levy testimony, the Commission did not expressly adopt Bresnahan's theories, but his rationale and the Commission's conclusions became one and the same. The Commission is quite comfortable with assenting to Bresnahan's rather

amorphous "incentive" theory despite its lack of empirical foundation.[19] Unfortunately, Bresnahan's so-called incentives do not rise to the level of legal conclusions. We understand that certain incentives may rank high in these transactions, but it also true that the possibility of an outside impetus often lays dormant. The simple presence of economic motive weighs little on the scale of probative value. See Serfeez v. Jewel Food Stores, 67 F.3d 591, 600-01 (7th Cir. 1995) ("The mere existence of mutual economic advantage, by itself, does not tend to exclude the possibility of independent, legitimate action and supplies no basis for inferring a conspiracy.").

The ALJ rejected the FTC's experts, concluding that testimony from Schering's witnesses "provides direct evidence that the parties did not exchange money for delay." The Commission disagreed, and determined that Niacor was not worth $60 million. To prove its point, the Commission relied on somewhat forced evidence: (1) the unconvincing fact that doctors gave Kos' niacin product mixed reviews, causing Schering to value those profits at an apparently contemptible $254 million; (2) the meretricious argument that Schering's personnel did not adequately assess Niacor's

[19] While the Commission's opinion conspicuously notes that it does not "adopt his terminology," it nonetheless endorses Bresnahan's incentive analysis: "We agree that there are strong monetary incentives for the pioneer and the generic to share the pioneer's substantial profits until the expiration of the patent, rather than compete head-to-head. The existence of these strong incentives, standing alone, obviously does not amount to proof of a law violation, but it may help to resolve conflicting inferences."

safety;[20] (3) the Commission's questionable non-expert opinion that Schering should have done more due diligence;[21] (4) the Commission's belief that the European market - where Schering held the Niacor license - for a niacin product was less desirable than the U.S. market;[22] and (5) Schering's post-settlement decision to discontinue its Niacor efforts in light of the poor sales effected by Kos' Niaspan.[23]

To borrow from the Commission's own words, we think its conclusion that Niacor was not worth $60 million, and that settlement payment was to keep Upsher off the market is "not supported by law or logic." Substantial evidence requires a review of the entire record at trial, and that most certainly includes the ALJ's

[20] In his testimony before the ALJ, Dr. Levy asserted that Niacor was toxic to the liver and criticized Schering for not taking liver biopsies on Upsher's clinical patients, who had long-since exited the trial program. Levy's later testimony revealed that he was not an expert in cholesterol-reducing drugs, and admitted that he "probably overstated" his opinion. The Commission's opinion emphasizes that it did not rely on Dr. Levy's testimony, yet again it arrives at the same conclusion, despite what we would presume to be a similar lack of knowledge in cholesterol-reducing drugs. It puzzles us that the Commission's opinion carefully traces Schering's due diligence and goes to great pains to highlight the intricate details, but still scolds Schering for not doing more.

[21] The Commission's opinion cited no authority for this assumption, but it also rejects "any suggestion that a reasonably adequate product review must necessarily take months, because the opportunity may no longer be on the table."

[22] This opinion was offered by a Kos official, who saw the U.S. market as "more appealing than the European market." Evidence shows, and even the FTC's experts agreed, that the worldwide market Schering had acquired rights to was at least as large as the U.S. market.

[23] Niaspan's sales were in fact disappointing. Market analysts predicted its 1999 sales to reach $169.3 million, and Schering's more conservative estimate calculated $101 million for the same year. In actuality, the sales were only $37.9 million.

credibility determinations and the overwhelming evidence that contradicts the Commission's conclusion. Universal Camera, 340 U.S. at 487-488, 496 (1951); see also Equifax Inc. v. FTC, 678 F.2d 1047, 1052 (11th Cir. 1982).

The ALJ made credibility findings based upon his observations of the witnesses' demeanor and the testimony given at trial. The Commission rejected these findings, and instead relied on information that was not even in the record. The Supreme Court has noted the importance of an examiner's determination of credibility, and explained that evidence which supports an administrative agency's fact-finding "may be less substantial when an impartial, experienced examiner who has observed the witnesses and lived with the case has drawn conclusions different from the [agency's]..." Id.[24] Additionally, the Court instructs that "[t]he findings of the examiner are to be considered along with the consistency and inherent probability of testimony." Id.

We think that this record consistently demonstrates the factors that Schering considered, and there is nothing to undermine the clear findings of the ALJ that this evidence was reliable. The Commission's finding that the "Upsher licenses were worth nothing to Schering" overlooks the very nature of the pharmaceutical industry

[24] At the time of the opinion in Universal Camera, an "examiner" performed the same functions as an ALJ.

where licenses are very often granted on drugs that never see the market.[25] Likewise, the essence of research and development is the need to encourage and foster new innovations, which necessarily involves exploring licensing options and selecting which products to pursue.

Finally, we note that the terms of the Schering-Upsher agreement expressly describes three payments totaling $60 million as "up-front royalty payments." The surrounding negotiations, trial testimony, and the record all evidence that both parties intended "royalty" to denote its traditional meaning: that Schering would pay Upsher for the licenses and production rights of Upsher's products. See e.g., Sierra Club, Inc. v. C.I.R., 86 F.3d 1526, 1531 (9th Cir. 1996) (noting that "'royalty' commonly refers to a payment made to the owner of property for permitting another to use the property") (citing Black's Law Dictionary 1330-31 (6th ed. 1979)). There is nothing to refute that these payments are a fair price for Niacor and the other Upsher products. Schering-Plough made a stand-alone determination that it was getting as much in return from these products as it was paying, and just because the agreement also includes Upsher's entry date into the potassium chloride supplement market, one cannot infer that the payments were solely for the delay rather than the licenses. See

[25] At trial, the FTC selected eight products that Schering had licensed from companies other than Upsher for comparative analysis. Five of those eight products were never marketed.

Valley Drug, 344 F.3d at 1309. Thus, the substantial and overwhelming evidence undercuts the Commission's conclusion that Schering's agreement with Upsher was illegal.

2. The ESI Settlement

The Commission separately addressed Schering's settlement with ESI. Although it purported to analyze this agreement under the same scheme as it did the Upsher settlement, there is far less development of the factual record to support the Commission's conclusion that the settlement was unreasonable. At trial, the FTC called no fact witnesses to testify about the ESI settlement, and its economic expert offered only brief testimony. The Commission's opinion itself spends little time on the ESI settlement, and begins with the recognition that the case is based on "relatively limited evidence." On the other hand, Schering produced experts who posited that Schering would have won the patent case, and that the ESI's January 1, 2004, entry date reasonably reflected the strength of Schering's case. The FTC did not rebut this testimony, but rather ignored it.

It seems the sole indiscretion committed in the context of the ESI settlement is the inclusion of monetary payments. The Commission ignored the lengthy mediation process, and insisted that the parties could have reached an alternative settlement with an earlier entry date. We do not pretend to understand the

Commission's profound concern with this settlement, but it takes particular exception to the $10 million payment, which was contingent on FDA approval of the generic product. The Commission also subtly questions the validity of the $5 million for legal costs. We might only guess that if the legal fee tallied $2 million - the arbitrary cap the Commission would allow for such settlements - it would not garner the same scrutiny.

The Commission, however, refused to consider the underlying patent litigation, and its certainty to be a bitter and prolonged process. All of the evidence of record supports the conclusion of the ALJ that this is not the case of a "naked payment" aimed to delay the entry of product that is "legally ready and able to compete with Schering." The litigation that unfolded between Schering and ESI was fierce and impassioned. Fifteen months of mediation demonstrates the doubt of a peaceful conclusion (or a simple compromise, as the Commission would characterize it).

That the parties to a patent dispute may exchange consideration to settle their litigation has been endorsed by the Supreme Court. See Standard Oil Co. v. United States, 283 U.S. 163, 170-71 n.5 (1931) (noting that the interchange of rights and royalties in a settlement agreement "may promote rather than restrain competition"). Veritably, the Commission's opinion would leave settlements, including those endorsed and facilitated by a federal court, with little confidence. The general policy

of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits. Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1368 (Fed. Cir. 2001); Foster v. Hallco Manufacturing Co., 947 F.2d 469, 477 (Fed. Cir. 1991); Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976). Patent owners should not be in a worse position, by virtue of the patent right, to negotiate and settle surrounding lawsuits. We find the terms of the settlement to be within the patent's exclusionary power, and "reflect a reasonable implementation" of the protections afforded by patent law. Valley Drug, 344 F.3d at 1312.

C. The Anticompetitive Effects

Our final line of inquiry turns to whether these agreements were indeed an "unfair method of competition." The FTC Act's prohibition on such agreements encompasses violations of other antitrust law, including the Sherman Act, which prohibits agreements in restraint of trade.15 U.S.C. § 45(c); California Dental Ass'n., 526 U.S. at 763 n.3. In California Dental, the Supreme Court required that the anticompetitive effect cannot be hypothetical or presumed. Rather, the probe must turn to "whether the effects actually are anticompetitive." Id. at 775 n.12.

The restraints at issue here covered any "sustained release microencapsulated potassium chloride tablet." Such a specific clause - an "ancillary restraint" - is routine to define the parameters of the agreement and to prevent future litigation over what

may or may not infringe upon the patent. See Rothery Storage & Van Co. v. Atlas Van Lines, Inc., 792 F.2d 210, 224 (D.C. Cir. 1986) ("The ancillary restraint is subordinate and collateral in the sense that it serves to make the main transaction more effective in accomplishing its purpose."). Ancillary restraints are generally permitted if they are "reasonably necessary" toward the contract's objective of utility and efficiency. See Law v. NCAA, 134 F.3d 1010, 1019 (10th Cir. 1998).

The efficiency-enhancing objectives of a patent settlement are clear, and "[p]ublic policy strongly favors settlement of disputes without litigation." Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976). See also Schlegal Mfg. Co. v. U.S.M. Corp., 525 F.2d 775, 783 (6th Cir. 1975) ("The importance of encouraging settlement of patent-infringement litigation...cannot be overstated."). In order for a condition to be ancillary, an agreement limiting competition must be secondary and collateral to an independent and legitimate transaction. Rothery Storage, 792 F.2d at 224. Naturally, the restraint imposed must relate to the ultimate objective, and cannot be so broad that some of the restraint extinguishes competition without creating efficiency. Even restraints ancillary in form can in substance be illegal if they are part of a general plan to gain monopoly control of a market. United States v. Addyston Pipe & Steel Co., 85 F. 271, 282-83 (6th Cir. 1898). Such a restraint, then, is not ancillary.

Under the Schering-Upsher agreement, the scope of the products subject to the September 1, 2001 entry date demonstrate an efficient narrowness. No other products were delayed by the ancillary restraints contained in the agreements. The '743 patent claims a "controlled release [microencapsulated] potassium chloride tablet." The language in the Schering-Upsher agreement covers the identical reach of the '743 patent. There is no broad provision that detracts from the efficiency of settling the underlying patent litigation. Nevertheless, the Commission rejected the notion that the narrow restraints were legitimate and reasonable means of accomplishing the settlement, and refused to consider that this settlement preserved public and private resources, and that the resultant certainty ultimately led to more intense competition.

The Commission's opinion requires the conclusion that but for the payments, the parties would have fashioned different settlements with different entry dates. Although it claimed to apply a rule of reason analysis, which we disagree with on its own, the Commission pointedly states that it logically concluded that "quid pro quo for the payment was an agreement by the generic to defer entry date beyond the date that represents an otherwise reasonable litigation compromise." We are not sure where this "logic" derives from, particularly given our holding in Valley Drug. "It is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit...litigation is a much more costly mechanism to

achieve exclusion, both to the parties and to the public, than is settlement." Id. at 1309.

The Commission rationalizes its decision not to consider the exclusionary power of the patent by asserting that the parties could have attained an earlier entry without the role of payments. There is simply no evidence in the record, however, that supports this conclusion. The Commission even recognized that the January 1, 2004 entry date in the ESI settlement was "non-negotiable." For its part, Schering presented experts who testified to the litigation truism that settlements are not always possible. Indeed, Schering's experts agreed that ancillary agreements may be the only avenue to settlement.

The proposition that the parties could have "simply compromised" on earlier entry dates is somewhat myopic, given the nature of patent litigation and the role that reverse payments play in settlements. It is uncontested that parties settle cases based on their perceived risk of prevailing in and losing the litigation. Pre-Hatch-Waxman, Upsher and ESI normally would have had to enter the market with their products, incurring the costs of clinical trials, manufacturing and marketing. This market entry would have driven down Schering's profits, as it took sales away. As a result, Schering would have sued ESI and Upsher, seeking damages for lost profits and willful infringement. Assuming the patent is reasonably strong, and the parties then

settled under this scenario, the money most probably would flow from the infringers to Schering because the generics would have put their companies at risk by making infringing sales.

By contrast, the Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from any possible infringement. See In re Ciprofloxacin Hydrochloride Antitrust Litigation, 261 F.Supp.2d 188, 251 (E.D.N.Y. 2003). Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Id. Because of the Hatch-Waxman scheme, ESI and Upsher gained considerable leverage in patent litigation: the exposure to liability amounted to litigation costs, but paled in comparison to the immense volume of generic sales and profits. This statutory scheme could then cost Schering its patent.

By entering into the settlement agreements, Schering realized the full potential of its infringement suit - a determination that the '743 patent was valid and that ESI and Upsher would not infringe the patent in the future. Furthermore, although ESI and Upsher obtained less than what they would have received from successfully defending the lawsuits (the ability to immediately market their generics), they gained more than if they had lost. A conceivable compromise, then, directs the consideration from the patent owner to the challengers. Id. Ultimately, the consideration paid to

Upsher and ESI was arguably less than if Schering's patent had been invalidated, which would have resulted in the generic entry of potassium chloride supplements.

In fact, even in the pre-Hatch-Waxman context, "implicit consideration flows from the patent holder to the alleged infringer." Id. If Schering had been able to prove damages from infringing sales, and settled before trial for a sum less than the damages, the result is a windfall to the generic manufacturers who essentially keep a portion of the profits. If this were true, then under the Commission's analysis, such a settlement would be a violation of antitrust law because the infringer reaped the benefit of the patent holder's partial surrender of damages. Like the reverse payments at issue here, "such a rule would discourage any rational party from settling a patent case because it would be an invitation to antitrust litigation." Id.

The Commission's inflexible compromise-without-payment theory neglects to understand that "[r]everse payments are a natural by-product of the Hatch-Waxman process." Id. Pure compromise ignores that patents, payments, and settlement are, in a sense, all symbiotic components that must work together in order for the larger abstract to succeed. As Judge Posner emphasized in Asahi, "[i]f any settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus classified as involving a forbidden 'reverse payment,'

we shall have no more patent settlements." Asahi Glass Co.. 289 F.Supp. 2d at 994. We agree. If settlement negotiations fail and the patentee prevails in its suit, competition would be prevented to the same or an even greater extent because the generic could not enter the market prior to the expiration of the patent. See In re Ciprofloxacin Hydrochloride Antitrust Litigation, 261 F.Supp.2d 188, 250-52 (E.D.N.Y.2003). A prohibition on reverse-payment settlements would "reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive." Ashai Glass Co., 289 F.Supp. 2d at 994.

There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation. See generally D. Crane, "Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications," 54 Fla. L. Rev. 747, 760 (2002). Patent litigation breeds a litany of direct and indirect costs, ranging from attorney and expert fees to the expenses associated with discovery compliance. Other costs accrue for a variety of reasons, be it the result of uncompromising legal positions, differing strategic objectives, heightened emotions, lawyer incompetence, or sheer moxie. Id.; see also, S. Carlson, Patent Pools and the Antitrust Dilemma, 16 Yale. J. Reg. 359, 380 (1999) (U.S. patent litigation costs $1 billion annually).

Finally, the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product. The intensified guesswork involved with lengthy litigation cuts against the benefits proposed by a rule that forecloses a patentee's ability to settle its infringement claim. See In re Tamoxifen Citrate Antitrust Litig., 277 F.Supp.2d 121, 133 (E.D.N.Y.2003) (noting that the settlement resolved the parties' complex patent litigation, and in so doing, "cleared the field" for other ANDA filers). Similarly, Hatch-Waxman settlements, likes the ones at issue here, which result in the patentee's purchase of a license for some of the alleged infringer's other products may benefit the public by introducing a new rival into the market, facilitating competitive production, and encouraging further innovation. See H. Hovenkamp, et al., Anticompetitive Settlement of Intellectual Property Disputes 87 Minn. L.Rev. at 1719, 1750-51 (2003); see also H. Hovenkamp Antitrust Law: An Analysis of Antitrust Principles and Their Application, ¶ 1780a (1999).

Despite the associated benefits of settlements - which include the avoidance of the burdensome costs and the resolution of uncertainty regarding the respective rights and obligations of party litigants - the Commission manufactured a rule that

would make almost any settlement involving a payment illegal.[26] Furthermore, the Commission's minimal allowance for $ 2 million in litigation costs is rather naive. While we agree that a settlement cannot be more anticompetitive than litigation, see Valley Drug, 344 F.3d at 1312, we must recognize "[a] suitable accommodation between antitrust law's free competition requirement and the patent regime's incentive system." 344 F.3d at 1307.

We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the "asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement." Id. at 1310. An exception cannot lie, as the Commission might think, when the issue turns on validity (Valley Drug) as opposed to infringement (the Schering agreements).[27] The effect is the same: a generic's entry into the market is delayed. What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection. Id. Here, we find that the agreements fell well within the protections of the '743 patent, and were therefore not

[26] Directly contrary to our opinion in Valley Drug.

[27] The Schering agreements would necessarily be stronger than those in Valley Drug, where the facts demonstrated the likelihood of an invalid patent, because a valid patent could operate to exclude all infringing products for the life of the patent.

illegal.

V. Conclusion

Valley Drug established the law in our Circuit. Simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannotbe the sole basis for a violation of antitrust law. This alone underscores the need to evaluate the strength of the patent. Our conclusion, to a degree, and we hope that the FTC is mindful of this, reflects policy. Given the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements, we fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date, and, in an ancillary transaction, pays for other products licensed by the generic. Such a result does not represent the confluence of patent and antitrust law. Therefore, this Court grants the petition for review. Accordingly, we SET ASIDE the decision of the Federal Trade Commission and VACATE its cease and desist order.

(二) TEVA PHARAMACEUTICALS v. NOVARTIS PHARAMACEUTICALS 案例原文

Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.C.A.Fed. (N.J.), 2007.Only the Westlaw citation is currently available.

United States Court of Appeals,Federal Circuit.

TEVA PHARMACEUTICALS USA, INC.,
Plaintiff-Appellant,
v.
NOVARTIS PHARMACEUTICALS CORPORATION, Novartis Pharma AG and Novartis International Pharmaceutical Ltd.,
Defendants-Appellees.
No. 06-1181.

March 30, 2007.

Appealed from United States District Court for the District of New Jersey, Judge Jose L. Linares.

Henry C. Dinger, Goodwin Procter LLP, of Boston, Massachusetts, argued for plaintiff-appellant. With him on the brief were Shepard M. Remis and Roland H. Schwillinski. Of counsel on the brief were Allyn Z. Lite and Michael E. Patunas, of Lite Depalma Greenberg & Rivas, LLC, of Newark, New Jersey.
Hugh C. Barrett, Fitzpatrick, Cella, Harper & Scinto, of New York, New York, argued for defendants-appellees. With him on the brief were Robert L. Baechtold, Nicholas N. Kallas, and Simon D. Roberts.

Before MAYER, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and GAJARSA, Circuit Judge.
GAJARSA, Circuit Judge.
Teva Pharmaceuticals ("Teva") appeals from the dismissal of its declaratory judgment action by the United States District Court for the District of New Jersey. The district court, relying on our two-part declaratory judgment test for patent non-infringement as modified by our recent decision in *Teva Pharmaceuticals USA, Inc., v. Pfizer, Inc.*, 395 F.3d 1324 (2005) ("*Pfizer* "), found that Teva failed to establish a reasonable apprehension of imminent suit and that it therefore lacked jurisdiction over the declaratory judgment action. In light of the Supreme Court's recent decision in *MedImmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764 (2007), which finds that our declaratory judgment test for non-infringement or invalidity "conflicts" with its precedent, we reverse.

I. BACKGROUND

Novartis holds a New Drug Application ("NDA") for three strengths of the drug Famvir® . Upon filing its Famvir® NDA, Novartis listed five patents in the Food and Drug Administration's ("FDA") Orange Book, each of which covers and is directed to various aspects of Famvir® , including U.S Patent Nos: 5,246,937 (" 937 patent"); 5,840,763 (" 763 patent"); 5,866,581 (" 581 patent"); 5,916,893 (" 893 patent"); and 6,124,304 (" 304 patent"). The 937 patent is directed to the active ingredient in Famvir® , famciclovir, while the remaining Orange Book patents are directed to methods of therapeutic use ("method patents") of Famvir® . The 937 patent expires in 2010, but the related therapeutic use patents do not expire until 2014-15.

In 2004, Teva filed an Abbreviated New Drug Application ("ANDA") with the FDA for generic famciclovir tablets in which Teva certified under paragraph IV of 21 U.S.C. § 355(j)(2)(A)(vii) that its drug did not infringe any of the five Novartis Famvir® Orange Book patents or that the patents were invalid. Teva's paragraph IV certifications constitute technical infringement under 35 U.S.C. § 271(e)(1). Accordingly, Novartis had 45 days to sue on these patents in order to invoke a statutorily mandated 30-month stay to delay immediate FDA approval of Teva's famciclovir ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

Novartis brought an infringement suit against Teva on the 937 patent alone and did not include in the action the related therapeutic use patents. The infringement suit is pending in the United States District Court for the District of New Jersey. *Novartis Pharm. Corp., v. Teva Pharm. USA, Inc.*, No. 05-1887 (D .N.J.2005).

After Novartis filed suit, Teva brought this declaratory judgment action on the four remaining method patents under 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5) to establish "patent certainty." Title 21 U.S.C. § 355(j)(5)(C) is a 2003 amendment to the ANDA statute entitled "civil action to obtain patent certainty." Under this provision, if the patentee or NDA holder does not bring an infringement suit within 45 days after receiving notice of a paragraph IV certification, the ANDA applicant may bring a civil action for a declaratory judgment that the patent at issue is invalid or will not be infringed by the drug for which the ANDA was submitted. *Id.* Title 35 U.S.C. § 271(e)(5) is a 2003 amendment to the patent statute that works in

conjunction with the 2003 amendment to the ANDA statute to provide that in a civil action to obtain patent certainty, federal courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought ... under § 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." Teva argues that by bringing suit on the 937 patent alone in the first instance, "Novartis has sought to put Teva to the hard choice of either launching at risk of massive liability for patent infringement when the 937 patent expires or Teva prevails in the pending infringement action, or foregoing that opportunity and thereby effectively extending the term of the 937 patent." Appellant Br. 9 (footnotes omitted).

Novartis moved to dismiss for lack of subject matter jurisdiction, arguing that Teva had no reasonable apprehension that it would be sued by Novartis for infringing the four method patents. In response, Teva argued that: (1) Novartis had already sued Teva on the underlying composition patent; (2) listing patents in the Orange Book established infringement as a matter of law; (3) Novartis had a history of aggressively suing generic drug companies; and (4) Novartis had declined to give Teva a covenant not to sue.

The district court dismissed Teva's declaratory judgment action requesting "patent certainty" on the four method patents. *Teva Pharm., USA, Inc., v. Novartis Pharm. Corp.*, No. 05-2881, slip op. at 10 (D.N.J. Dec. 12, 2005). In so doing, the district court applied our two prong "reasonable-apprehension-of-imminent-suit" test from *Pfizer*.[FN1] 395 F.3d at 1332. After comparing the facts of this case to those in *Pfizer*, the district court found that Teva had failed to establish a reasonable apprehension of imminent suit and that the district court therefore lacked jurisdiction over the declaratory judgment action. *Teva*, slip op. at 10. Teva timely appealed to this court. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

FN1. Under this two prong test, the ANDA declaratory judgment plaintiff must show both: (1) a "reasonable apprehension" of "imminent" suit by the patentee; and (2) activity constituting infringement or the intent to infringe. *See Pfizer*, 395 F.3d at 1332.

The district court's dismissal of Teva's declaratory judgment action for lack of jurisdiction presents a question of law that we review without deference. *See Pfizer*, 395 F.3d at 1332 (citing *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1379 (Fed.Cir.2004)). The determination of whether an actual controversy exists under the Declaratory Judgment Act in a patent case is a question of law that we review *de novo*. *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed.Cir.1993). The district court's factual findings supporting its determination are reviewed for clear error. *Id.*

II. ANALYSIS

A.

Our starting point in analyzing Teva's appeal is the Declaratory Judgment Act, 28 U.S.C. § 2201(a) under which Teva filed this suit. The relevant text of the Act reads:

> In a case of actual controversy within its jurisdiction ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

28 U.S.C. § 2201(a).

In the ANDA context, Congress explicitly extended federal court declaratory judgment jurisdiction under 28 U.S.C. § 2201 to ANDA paragraph IV disputes such as Teva's and did so "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5).[FN2]

FN2. The Declaratory Judgment Act and 35 U.S.C. § 271(e)(5) "serve [ ] the policies underlying the patent laws by enabling a test of the validity and infringement of patents that are ... being used only as ... 'scarecrows.' " *Arrowhead Indus. Water, Inc. v. Ecolochem*, 845 F.2d 731, 735 (1988) (quoting Judge Learned Hand in *Bresnick v. U.S. Vitamin Corp.*, 139 F.2d 239 (2d Cir.1943)). Before the declaratory judgment provisions, competitors were "victimized" by patent owners who engaged in "extrajudicial patent enforcement with scare-the-customer-and-run tactics that infect[ed] the competitive environment of the business community with uncertainty and insecurity" and that rendered competitors "helpless and immobile so long

> as the patent owner refused to ... sue." *Id.* at 735 (quoting *Japan Gas Lighter Ass'n v. Ronson Corp.*, 257 F.Supp. 219, 237 (D.N.J.1966)). After enactment of these provisions, competitors "were no longer restricted to [the hard] choice between incurrence of a growing potential liability for patent infringement and abandonment of their enterprises; they could clear the air by suing for a [declaratory] judgment." *Id.*

The Supreme Court recently re-affirmed that the Act's "actual controversy" requirement "refers to the type of 'Cases' and 'Controversies' that are justiciable under Article III." *MedImmune*, 127 S.Ct. at 771 ("[T]he phrase 'case of actual controversy' in the Act refers to the type of 'Cases' and 'Controversies' that are justiciable under Article III.") (citing *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937)).

In *MedImmune*, the Court found that its precedent "did not draw the brightest of lines between those declaratory-judgment actions that satisfy the case-or-controversy requirement and those that do not." *Id.* Instead of applying a bright line, the Court stated that its decisions required:
that the dispute be "definite and concrete, touching the legal relations of the parties having adverse legal interests"; and that it be "real and substantial" and "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts."

Id. (citing *Aetna Life Ins. Co.*, 300 U.S. at 240-41).

Previously, the Court held that "the difference between an abstract question and a 'controversy' contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy." *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941). In *MedImmune*, the Court re-affirmed the correct standard for determining a justiciable declaratory judgment action: "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* (citing *Md. Cas. Co.*, 312 U.S. at 273).

Thus, *MedImmune* teaches that in a declaratory judgment action, "all the circumstances" must demonstrate that a justiciable Article III "controversy" exists. A justiciable Article III controversy requires the party instituting the action to have standing and the issue presented to the court to be ripe. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

Article III standing requires "[a] plaintiff [to] allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *Allen v. Wright*, 468 U.S. 737, 751 (1984). Of the three standing requirements, injury-in-fact is the most determinative: "[W]hatever else the 'case or controversy' requirement embodie [s], its essence is a requirement of 'injury in fact.' " *Schlesinger v. Reservists Comm. to Stop the War*, 418 U.S. 208, 218 (1974) (citing *Ass'n of Data Processing Serv. Org., Inc. v. Camp*, 397 U.S. 150, 152 (1970)). An injury-in-fact must be "personal," "concrete and particularized," and "actual or imminent." *Lujan*, 504 U.S. at 560; *Warth v. Seldin*, 422 U.S. 490, 501 (1975).

Under the declaratory judgment standard, "all the circumstances" must demonstrate the Article III justiciability requirement that the case be ripe for judicial review. *Abbott Labs. v. Gardner*, 387 U.S. 136 (1967). The doctrine of ripeness focuses on the conduct of the defendant to determine whether the defendants actions have harmed, are harming, or are about to harm the plaintiff. Ripeness can be an issue in obtaining anticipatory relief like declaratory judgments. *Id.* at 149. A "controversy" is "ripe" if the question presented is "fit for judicial review," meaning it is entirely or substantially a question of law and postponing a decision would work a substantial hardship on the challenging party. *Id.* at 149-50 (applying the test and holding that a regulation requiring drug manufacturers to change labeling was ripe for review before it was enforced because the regulation had an immediate and expensive impact on the plaintiffs' operations and plaintiffs risked a substantial sanction for non-compliance).

Similar to the ripeness doctrine and based on the same constitutional "controversy" requirement is the Court's prohibition against advisory opinions. Under this doctrine, federal courts are to decide only "actual controversies by judgment which can be carried into effect, and not to give opinions upon moot questions or abstract propositions, or to declare principles or rules of law which cannot affect the matter in the case before it." *Local No. 8-6, Oil, Chem. & Atomic Workers Int'l Union v. Missouri*, 361 U.S. 363, 367

(1960). Although there can be a fine line between declaratory judgments and advisory opinions, the Supreme Court maintains the necessity of avoiding issuing advisory opinions based upon hypothetical facts. *Elec. Bond & Share Co. v. Sec. & Exch. Comm'n*, 303 U.S. 419 (1938).

Notwithstanding the Court's justiciability precedent, it is well established that Congress by legislation "may expand standing to the full extent permitted by [A]rticle [III] of [the] Constitution, thus permitting litigation by one who otherwise would be barred." *Gladstone Realtors v. Vill. of Bellwood*, 441 U.S. 91, 100 (1979). Congress, however, cannot expand standing beyond the Article III jurisdiction of federal courts. *Id.* Thus, as long as Congress remains within constitutional limits, it may "enact statutes creating legal rights, the invasion of which creates standing, even though no injury would exist without the statute." *Linda R.S. v. Richard D.*, 410 U.S. 614, 617 n. 4 (1973) (citing *Trafficante v. Metro. Life Ins. Co.*, 409 U.S. 205, 212 (1972) (White, J., concurring)).

The Declaratory Judgment Act and 35 U.S.C. § 271(e)(5) are examples of legislation that expand standing to constitutional limits and provide a way for plaintiffs to bring actions in federal court when they might otherwise be barred. The sole requirement for federal court jurisdiction under both provisions is an "actual controversy," 28 U.S.C. § 2201(a), which is the same as an Article III case or controversy. *See Aetna Life Ins.*, 300 U.S. at 239-41. This means that under both provisions, a declaratory judgment plaintiff is only required to satisfy Article III, which includes standing and ripeness, by showing under "all the circumstances" an actual or imminent injury caused by the defendant that can be redressed by judicial relief and that is of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 127 S.Ct. at 771 (internal citations omitted). [FN3]

FN3. However, unlike non-declaratory judgment actions, even if there is an actual controversy, the district court is not required to exercise jurisdiction to address the merits of the action, as it retains discretion under the Act to decline declaratory judgment jurisdiction. *Public Serv. Comm'n v. Wycoff Co.*, 344 U.S. 237, 241 (1952); *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed.Cir.1991) ("When there is no actual controversy, the court has no [jurisdiction and no] discretion to decide the case. When there is an actual controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary.").

In the instant case, we follow the Court's analysis in *MedImmune* in determining whether Teva has a justiciable controversy within the meaning of Article III. *Id.* By following *MedImmune*, we recognize that we are not relying on our two-part reasonableapprehension-of-suit test. *See, e.g., Pfizer*, 395 F.3d at 1332-33. This court respects the principle of stare decisis and follows its own precedential decisions unless the decisions are "overruled by the court en banc, or by other controlling authority such as an intervening ... Supreme Court decision." *Tex. Am. Oil Co. v. U.S. Dep't of Energy*, 44 F.3d 1557, 1561 (Fed.Cir.1995) (en banc).

Under our patent jurisprudence, we developed a two-part test to determine if an "actual controversy" exists in a general declaratory judgment action for patent non-infringement or invalidity. *See, e.g., Pfizer*, 395 F.3d 1332-33. This test requires both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such an activity. *See, e.g ., id.*

In *MedImmune*, the Supreme Court in a detailed footnote stated that our two-prong "reasonable apprehension of suit" test "conflicts" and would "contradict" several cases in which the Supreme Court found that a declaratory judgment plaintiff had a justiciable controversy.[FN4] 127 S.Ct. at 774 n. 11. In *MedImmune*, the Court disagreed with our "reasonable apprehension of imminent suit" test and re-affirmed that the "actual controversy" requirement in the Declaratory Judgment Act is the same as the "Cases" and "Controversies" requirement in Article III. *Id.* at 771. The Court further re-affirmed that an "actual controversy" requires only that a dispute be " 'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical set of facts.' " *Id.* (quoting *Aetna Life Ins. Co.*, 300 U.S. at 240-41). The Court summarized the declaratory judgment "actual controversy" requirement by quoting the "all the circumstances" test from *Maryland Casualty*. *Id.* Thus, because the Supreme Court in *MedImmune* cautioned that our declaratory judgment

"reasonableapprehension-of-suit" test "contradict[s]" and "conflicts" with its precedent, these Federal Circuit tests have been "overruled by ... an intervening ... Supreme Court decision." *Tex. Am. Oil Co.*, 44 F.3d at 1561; *see also, SanDisk v. STMicroelectronics*, --- F.3d ----, 2007 WL 881008 (Fed.Cir. Mar. 26, 2007). Therefore, we follow *MedImmune's* teaching to look at "all the circumstances" under *Maryland Casualty* to determine whether Teva has a justiciable Article III controversy.

> FN4. *See, e.g., Md. Cas. Co.*, 312 U.S. at 273 (finding a justiciable controversy even though the collision-victim defendant could not have sued the declaratory-judgment plaintiff-insurer without first obtaining a judgment against the insured); *Aetna Life Ins. Co.*, 300 U.S. at 239 (finding a justiciable controversy even though the very reason the insurer sought declaratory relief was that the insured had given no indication that he would file suit); *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 98 (1993) (holding that appellate affirmance of a judgment of non-infringement, eliminating any apprehension of suit, does not moot a declaratory judgment counterclaim of patent invalidity).

B.

The district court was bound by our precedent in *Pfizer* to apply the "reasonable-apprehension-of-imminent-suit" test to Teva's declaratory judgment action. Teva, slip op. at 9. In applying this test, the district court considered Teva's standing and concluded that Teva had failed to establish the type of injury-in-fact that we required in *Pfizer* because Teva could not show a reasonable apprehension of imminent suit. Teva, slip op. at 9; *see Pfizer*, 395 F.3d at 1333 (requiring a showing of *"imminent* suit"). The district court found that because Teva could not establish an Article III controversy under our precedent, it did not have jurisdiction and dismissed Teva's declaratory judgment action.

We hold that *MedImmune* applies to Teva's declaratory judgment action and takes precedence over the district court's application of *Pfizer*, which required Teva to show a single type of Article III injury-in-fact, "a reasonable apprehension of imminent suit." 395 F.3d at 1333. The question in this case is whether Teva has a justiciable controversy within Article III, which is the only limitation on our jurisdiction under the Declaratory Judgment Act. *See* 28 U.S.C § 2201. An Article III controversy is found where a plaintiff has demonstrated an injury-in-fact caused by the defendant that can be redressed by the court. *See Steel Co.*, 523 U.S. at 83. In the present case, only the concrete injury-in-fact requirement under Article III is in dispute.

We hold that under "all the circumstances" as found in this case, Teva has an injury-in-fact and therefore has a justiciable Article III controversy. Here, Novartis argues that there is no actual controversy between it and Teva on the four method patents in spite of Teva's paragraph IV certifications of the four method patents because Novartis has not filed suit nor threatened to sue Teva on the method patents. Moreover, Novartis contends that the suit on the 937 patent is an entirely different controversy. Novartis is incorrect. There is no question that Novartis has already filed suit based on Teva's act of infringement in submitting the ANDA. Under 35 U.S.C. § 271(e)(2)(A), submitting an ANDA, regardless of how many paragraph IV certifications it may contain, is a single act of infringement: "It shall be *an act* of infringement to submit-an [ANDA] application ... for a drug claimed in a patent or for the use of which is claimed in a patent." (Emphasis added). While it is true that the suit on the 937 patent is a different "case" than Teva's declaratory judgment action, Novartis created a present and actual "controversy" by choosing to sue under 35 U.S.C. § 271(e)(2)(A) on Teva's single act of infringement, thereby placing into actual dispute the soundness of Teva's ANDA and Teva's ability to secure approval of the ANDA. Thus, while Teva's declaratory judgment action and the pending 937 suit are different "cases," they arise from the same controversy created when Novartis listed its Famvir® patents in the Orange Book, Teva submitted its ANDA certifying all five Famvir® patents under paragraph IV, and Novartis sued Teva challenging the submission of Teva's ANDA.[FN5]

> FN5. In analyzing Novartis' election not to sue on the four method patents, it appears from the greater part of the district court's analysis that the district court may have erred in explaining the purpose of the 45-day statutory "window" in 21 U.S.C. § 355(j)(5)(B)(iii). The provision provides an automatic 30-month stay of approval of an

> ANDA if an infringement action is brought by a patent holder within 45 days against the ANDA filer on a patent it has certified under paragraph IV; if no suit is brought the ANDA is immediately approved. *Id.* The district court seemed to incorrectly interpret this provision as a waiver, finding that Novartis had only a 45-day window in which to sue Teva on all the paragraph IV patents in Teva's ANDA, and because Novartis had allowed this window to expire, it could not bring suit on the four remaining method patents. *Teva,* slip op. at 7, 9-10. This is not what the statute provides. Novartis' selective action against Teva is an attempt by Novartis to limit the impact of Teva's ANDA under the Hatch-Waxman Act, while at the same time using it to forestall a challenge on all the remaining four method patents. By suing solely on the 937 patent, Novartis has not only invoked the 30-month stay, preventing Teva's entire ANDA from immediate approval, but Novartis is also selectively suing on the patent with the earliest expiration date leaving the remaining four method patents overhanging Teva for future litigation. This conduct prevents Teva's generic from entering the market until the expiration of the last patent and is directly contrary to the purpose of the 30-month stay. The stay is explicitly offered to patent holders who "reasonably cooperate in expediting [ ] action[s]" challenging their patents. 21 U.S.C. § 355(j)(5)(B)(iii).

Novartis' conduct raises the questions of if and how 35 U.S.C. § 271(e)(2) applies to multiple suits between the same parties on the submission of a single ANDA with more than one paragraph IV certification. It is clear from the statutory language that recovering damages for a 35 U.S.C. § 271(e)(2)(A) infringement action is only time barred by the statutory six-year statute of limitations. *See* 35 U.S.C. § 286 ("[N]o recovery shall be had for any infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action."); *see also, A.C. Aukerman Co. v. R.L. Chaides Const. Co .*, 960 F.2d 1020, 1030 (Fed.Cir.1992) (explaining that § 286 is "not a statute of limitations in the sense of barring a suit for infringement" ... but rather a "limit to recovery to damages for infringing acts committed within six years of the date of the filing of the infringement action."). Thus, Novartis has the right of an immediate action against Teva under 35 U.S.C. § 271(e)(2)(A) on any or all of the remaining Famvir® Orange Book patents.[FN6] These actions could be brought at any time until the patents expire and damages would be limited only by the six-year limitations period. While it is unclear whether Novartis would be prohibited from suing under the doctrine of claim preclusion, Teva remains under the threat of an infringement suit because the 45-day statutory window does not preclude Novartis from pursuing additional infringement suits under 35 U.S.C. § 271(e)(2)(A). In light of Novartis' pending suit on the same ANDA, this threat of litigation is a present injury creating a justiciable controversy. Moreover, Novartis retains the right to sue Teva under the Famvir® patents pursuant to 35 U.S.C. § 271(a). Therefore, Novartis has numerous opportunities to bring an action at any time for patent infringement and is not precluded by the 45-day window.

> FN6. Teva filed its ANDA with the five paragraph IV certifications on December 28, 2004, resulting in the single act of infringement under 35 U.S.C. § 271(e)(2)(A).

The district court erred in finding that *Teva* did not demonstrate an Article III controversy. Teva, slip op. at 6-10. A justiciable controversy can arise from either an actual or an imminent injury. While it is true that several of Teva's grounds alleging an "actual controversy" when standing alone might not be sufficient, if taken as a whole these circumstances establish a justiciable controversy with Novartis that can be resolved by allowing Teva to bring a declaratory judgment.

First, Novartis listed its Famvir® patents in the Orange Book. By so doing, Novartis represents that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale" of generic famciclovir covered by the claims of its listed Famvir® patents. 21 U.S.C. § 355(b)(1); *see Pfizer,* 395 F.3d at 1341 (Mayer, J., dissenting). While this conduct on its own may not be sufficient to establish an Article III controversy, it is a circumstance to be considered in determining whether a justiciable controversy exists under the totality of the circumstances.

A second circumstance that supports Teva's claim of a justiciable controversy is Teva's submission of its ANDA certifying that it did not infringe Novartis'

Famvir® Orange Book patents or that the patents were invalid. The very act of submitting an ANDA is an act of infringement. 35 U.S.C. § 271(e)(2); *see Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (holding that the statute creates an "act of infringement that consists of submitting an ANDA ... containing the fourth type of certification"). There is no question that under 35 U.S.C. § 271(e)(2), Novartis would have an immediate justiciable controversy against Teva as soon as Teva submitted the ANDA; indeed, that is exactly what occurred in this case. It logically follows that if such an action creates a justiciable controversy for one party, the same action should create a justiciable declaratory judgment controversy for the opposing party. In fact, the Supreme Court has stated: "It is immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit are reversed; the inquiry is the same in either case." *Md. Cas. Co.*, 312 U.S. at 273. This conclusion is supported in the legislative history of the 2003 "civil action to obtain patent certainty" amendment to the Hatch-Waxman Act:

[T]he Hatch-Waxman Act has always provided that patent owners and brand drug companies can bring patent infringement suits against a generic applicant immediately upon receiving notice that the generic applicant is challenging a patent [by filing an ANDA]. The [ANDA] declaratory judgment provisions ... simply level the playing field by making it clear that the generic applicant can also seek a prompt resolution of these patent issues by bringing a declaratory judgment action if [it is not sued] ... within 45 days.

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of the Senate HELP committee).

A third circumstance we find relevant in determining whether Teva has established an actual controversy is the combination of three statutory provisions: 1) the "civil action to obtain patent certainty" under 21 U.S.C. § 355(j)(5)(C); 2) the ANDA declaratory judgment provision under 35 U.S.C § 271(e)(5); and 3) the purpose of the Hatch-Waxman Act. The "civil action to obtain patent certainty," which was enacted in 2003 is designed to prevent patentees from "gaming" the Hatch-Waxman Act.[FN7] *See* 21 U.S.C. § 355(j)(5)(C). This amendment specifically permits an ANDA applicant to file a declaratory judgment action under 28 U.S.C. § 2201 against the patent owner or the brand-name drug company "for a declaratory judgment that the patent [listed in the Orange Book] is invalid or will not be infringed by the drug" covered by the ANDA if the patentee has not brought an infringement action within 45 days. *Id.* By virtue of 35 U.S.C § 271(e)(5), Congress extended federal court jurisdiction over these ANDA declaratory judgment actions "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5).

> FN7. "[I]n recent years both brand-name and generic drug companies have exploited certain aspects of the Hatch-Waxman Act to delay generic competition. The changes to the [ ] Act ... will stop these abuses." 149 Cong. Rec. S15882-03, S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of the Senate HELP committee).

By filing a lawsuit on only one its five patents certified under paragraph IV in Teva's ANDA, Novartis has tried to simultaneously leverage the benefits provided to a patentee under the Hatch-Waxman Act and avoid the patentee's accompanying responsibilities. Novartis' 937 patent suit against Teva has invoked the statutory automatic 30-month stay and is concurrently insulating the four method patents from a validity challenge. In the statute, Congress explicitly required that in exchange for the 30-month stay, patentees were to "reasonably cooperate in expediting the action" of whether the paragraph IV patents were invalid or not infringed.[FN8] 21 U.S.C. § 355(j)(5)(B)(iii). Novartis' action insulates it from any judicial determination of the metes and bounds of the scope of the claims of its four Famvir® method patents in relation to design-around, a determination that is central to the proper function of our patent system and is a central purpose of the Hatch-Waxman Act. *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 405 F.3d 990, 992 (Fed.Cir.2005) (rehearing en banc denied) (Gajarsa, J., dissenting).

> FN8. A patent owner who brings an infringement claim against an ANDA filer within the 45-day period invokes an automatic 30-month stay preventing the otherwise immediate approval of the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). The stay provides a safety net and an incentive to patentees who would otherwise not be inclined to bring a suit against the generic because at the time the ANDA is filed, the patentee has not suffered any economic loss. Where no commercial activity has yet taken place, a patentee becomes susceptible to

> having its patent found invalid or not infringed.

It is clear from the legislative history that Congress intended this "civil action" to adjudicate the very controversy that Novartis has created here:

> The provision [a "civil action to obtain patent certainty"] ... is intended to clarify that Federal district courts are to entertain such suits for declaratory judgments so long as there is a "case or controversy" under Article III of the Constitution. We fully expect that, in almost all situations where a generic applicant has challenged a patent [by filing an ANDA with a paragraph IV certification] and not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable "case or controversy" under the Constitution. We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe.
>
> The mere fact that neither the patent owner nor the brand drug company has brought a patent infringement suit within 45 days against a generic applicant does not mean there is no "case or controversy." The sole purpose of requiring the passage of 45 days is to provide the patent owner and brand-name drug company the first opportunity to begin patent litigation. Inaction within the 45-day period proves nothing, as *there are tactical reasons why a patent owner or brand drug company might refrain from bringing suit on a patent within 45 days. For example, the brand drug company might have several patents listed in the Food and Drug Administration's Orange Book with respect to a particular drug. It could be in the company's interest to bring suit within 45 days on one patent and to hold the others in reserve.* The suit on one patent would automatically stay approval of the generic application until the lawsuit is resolved or the 30 months elapses. Holding the other patents in reserve would introduce uncertainty that could discourage generic companies from devoting resources to bring the generic drug to market and that would give the brand drug company a second opportunity to delay generic competition by suing the generic company for infringement of the reserved patents after the resolution of the initial infringement suit.
>
> In each of these and in other circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon the expiration of the 45-day period. We believe there can be a case or controversy sufficient for courts to hear these cases merely because the patents at issue have been listed in the FDA Orange Book, and because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes. The declaratory judgment provisions in this bill are intended to encourage such early resolution of patent disputes.

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of Senate HELP committee) (emphasis added). A central purpose of the Hatch-Waxman Act and the subsequent ANDA declaratory judgment amendment to that Act is "to enable competitors to bring cheaper, generic ... drugs to market as quickly as possible." *Id.* Novartis' actions frustrate this purpose and create a basis for finding a justiciable controversy.

A fourth circumstance contributing to Teva's justiciable controversy is Novartis' pending infringement litigation. *See Novartis Pharm. Corp.*, No. 05-1887. As stated previously, Novartis' suit against Teva on Teva's submitted ANDA is an Article III controversy. A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents. Our conclusion supports what we have already established in non-ANDA cases-that related litigation involving the same technology and the same parties is relevant in determining whether a justiciable declaratory judgment controversy exists on other related patents. *See* Vanguard Research, Inc. v. Peat, Inc., 304 F.3d 1249, 1255 (Fed.Cir.2005) (following *Goodyear* and finding a justiciable declaratory judgment controversy where the defendant had sued the declaratory judgment plaintiff for misappropriation of trade secrets thereby demonstrating "a willingness to protect [its] technology."); Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 955 (Fed.Cir.1987) (finding a justiciable declaratory judgment controversy in a patent non-infringement and invalidity action where the defendant had sued the declaratory judgment plaintiff in state court for misappropriation of trade secrets involving the same technology, thereby engaging in "a course of conduct

that shows a willingness to protect that technology.").

Novartis' selective 937 suit creates uncertainty as to Teva's legal rights under its ANDA. Ordinarily, a potential competitor in other fields is legally free to market its product in the face of an adversely-held patent. In contrast, under the Hatch-Waxman Act an ANDA filer in Teva's situation is not legally free to enter the market because federal statutes prohibit it. *See* 21 U.S.C § 355(j)(5)(B)(iii). Hence, Teva suffers a direct legal injury from the actions that Novartis has already taken-Novartis' listing of the five Famvir® patents in the Orange Book and Novartis' suit against Teva challenging the validity of Teva's ANDA-which requires judicial relief. It is this exact type of uncertainty of legal rights that the ANDA declaratory judgment action was enacted to prevent. *See id.* § 355(j)(5)(C). Congress clearly has authority to give standing and create justiciable injuries through legislation for parties that might otherwise have no recourse as long as Congress does not exceed the limitations of Article III. *Gladstone*, 441 U.S. at 100 ("Congress may, by legislation, expand standing to the full extent permitted by Art. III, thus permitting litigation by one 'who otherwise would be barred ....' " (internal citations omitted)). Congress created the ANDA declaratory judgment action for generic drug companies specifically to avoid the type of legal uncertainty that Novartis has created. The legislative history of the ANDA declaratory judgment amendment explicitly states that the "uncertainty" caused by a brand-name company when it chooses to sue on only selective patents submitted in a single ANDA is an injury sufficient to support a justiciable controversy. *See* 149 Cong. Rec. S15885 (Nov. 25, 2003). The type of legal uncertainty as to the legal status of Teva's ANDA that Novartis has created by suing on only one of the five paragraph IV certified Famvir® patents listed in the Orange Book is a present injury sufficient for a justiciable controversy.

Finally, the possibility of future litigation that Novartis created by electing to challenge Teva's ANDA on only one of the five Orange Book listed Famvir® patents is a fifth circumstance contributing to finding that Teva has a justiciable declaratory judgment controversy. Novartis' suit on the 937 patent alone leaves open the possibility of future litigation regardless of whether Teva wins or loses the 937 infringement suit. The possibility that an ANDA filer will be subject to multiple infringement suits from the same patentee based on the submission of a single ANDA containing several paragraph IV certifications is an injury relevant to finding a justiciable controversy. If Teva is successful in defending the pending 937 infringement suit, it remains subject to four additional infringement actions by Novartis under 35 U.S.C. § 271(e)(2) on the remaining Famvir® Orange Book patents certified in Teva's ANDA under paragraph IV. By its action, Novartis is insulating its Famvir® Orange Book patents from any challenge of invalidity or non-infringement until all the patents expire. This threat of protracted litigation creates a present and real harm that is a relevant circumstance in finding whether a justiciable controversy exists.

III. CONCLUSION

The Court re-affirmed in *MedImmune* the "all circumstances" analysis as the correct standard to use in determining whether a justiciable Article III controversy exists in a declaratory judgment action. Under this standard, we find that Teva has an injuryin-fact and a justiciable controversy that can be fully resolved by a declaratory judgment. Allowing Teva's declaratory judgment action is consistent with the "controversy" requirement in Article III and the Declaratory Judgment Act because the suit will achieve a final determination that resolves the entire dispute between Teva and Novartis. Teva has experienced real and actual injury. Consequently, Teva's injuries are traceable to Novartis' conduct and those injuries can be redressed by a favorable judicial decision. Therefore, Teva has established standing and an actual controversy sufficient to confer jurisdiction under the Declaratory Judgment Act.

For these reasons we reverse the district court's decision dismissing Teva's declaratory judgment action.

REVERSED

Concurring opinion filed by Senior Circuit Judge FRIEDMAN.FRIEDMAN, Senior Circuit Judge, concurring in the judgment.
I agree with the court that the appellant Teva Pharmaceuticals USA, Inc. ("Teva") has shown an "actual controversy" under the Declaratory Judgment Act, 28 U.S.C. § 2201(a), and that the district court's judgment dismissing Teva's declaratory judgment action for lack of jurisdiction should be reversed. I write separately because I take a somewhat different, and shorter, path than the court does in reaching that conclusion.

In *MedImmune, Inc., v. Genentech, Inc.*, 549 U.S. ----

(2007), the Supreme Court rejected this court's settled view that a patent licensee must "terminate or be in breach of its license agreement before it can seek a declaratory judgment that the underlying patent is invalid, unenforceable, or not infringed." *Id.*, slip op. at 1; *see Gen-Probe Inc. v. Vysis,* 359 F.3d 1376 (Fed.Cir.2005). The Supreme Court ruled that the jurisdiction of the district court did not turn on whether the declaratory judgment plaintiff had stopped paying royalties under or otherwise terminated the license, but on the general broader principles governing declaratory judgment jurisdiction, namely, whether the dispute between the parties is " 'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.... Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.' " *MedImmune,* slip op. at 7-8 (citation and footnote omitted).

In a somewhat detailed footnote, the Supreme Court stated that this court's " 'reasonable apprehension of *imminent* suit' test" for determining declaratory judgment jurisdiction in patent cases (*see Teva Pharms., USA, Inc. v. Pfizer,* 395 F.3d 1324, 1333 (2005)) "would still contradict" a prior Supreme Court case and also "conflict[ ]" with another Supreme Court case, both of which that Court had relied on in its license breach ruling. *Id.*, slip op. at 13 n. 11. Although these footnote statements were dicta, the Court apparently was telling us that it rejected our "reasonable apprehension of *imminent* suit" test for determining declaratory judgment jurisdiction in patent cases, and that the broader general rules governing declaratory judgment jurisdiction also govern patent cases.

In these unusual circumstances, where the Supreme Court went out of its way to state its disagreement with our "reasonable apprehension of *imminent* suit" test, which was not an issue in the case before it, it appears incumbent on us to stop using that test and hereafter to apply the general declaratory judgment standards that the Supreme Court applied in *Medimmune.*

I agree with the court that under these general standards there was an "actual controversy" between Teva and Novartis about the infringement and validity of the four patents relating to the Famvir® technology. All five of Novartis' Famvir® patents are closely related. As this court here recognizes, by listing those five patents in the Orange Book, "Novartis represent[ed] that a 'claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale' of generic famciclovir covered by the claims of its listed Famvir® patents." Maj. Op. at 15. In its Abbreviated New Drug Application filed with the Food and Drug Administration, Teva certified under paragraph IV of 21 U.S.C. § 355(j)(2(A)(vii) that "its drug did not infringe" any of the five Novartis Famvir® Orange Book patents or that the patents were invalid. There thus is an existing controversy between the parties over whether Teva's generic version of Famvir® would infringe the four other Famvir® patents listed in the Orange Book, and whether these patents are valid. Novartis' filing of the suit charging that Teva has infringed one of those five patents and Teva's filing a declaratory judgment suit relating to the other four patents confirms that the controversy between the parties is continuing.

C.A.Fed. (N.J.),2007.
Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.
--- F.3d ----, 2007 WL 942201 (C.A.Fed. (N.J.))

END OF DOCUMENT

(三) PFIZER INC. v. DR. REDDY'S LABORATORIES 案例原文

United States Court of Appeals for the Federal Circuit

03-1227, -1258

PFIZER INC.,

Plaintiff-Appellant,

v.

DR. REDDY'S LABORATORIES, LTD.
and DR. REDDY'S LABORATORIES, INC.,

Defendants-Appellees.

Glen D. Nager, Jones Day, of Washington, DC, argued for plaintiff-appellant. With him on the brief were Gerald Sobel, and Milton Sherman, Kaye Scholer LLP, of New York, New York; and Gregory A. Castanias and David O. Bickart, Kaye Scholer LLP, of Washington, DC. Of counsel on the brief was David E. De Lorenzi, Gibbons, Del Deo, Dolan, Griffinger & Vecchione, of Newark, New Jersey.

Brian T. Moriarty, Budd Larner Rosenbaum Greenberg & Sade, of Short Hills, New Jersey, argued for defendants-appellees. With him on the brief were Andrew J. Miller, Nicholas A. Tyacke, Jacquelyn Inserra, and Vijayant Pawar.

David G. Conlin, Edwards & Angell, LLP, of Boston, Massachusetts, for amicus curiae Takeda Chemical Industries, Ltd. With him on the brief were Barbara L. Moore, Kathleen B. Carr, and B. Stephanie Siegmann.

John F. Lynch, Howrey Simon Arnold & White, LLP, of Houston, Texas, for amicus curiae Merck & Co., Inc. With him on the brief were Nicolas G. Barzoukas and Richard L. Stanley. Of counsel on the brief were Paul D. Matukaitis, Edward W. Murray, and Gerard M. Devlin, Merck & Co., Inc., of Rahway, New Jersey.

Allen M. Sokal, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, for amicus curiae Wyeth. With him on the brief was Gregory A. Chopskie. Of counsel on the brief was David A. Manspeizer, Wyeth, of Madison, New Jersey.

E. Edward Bruce, Covington & Burling, of Washington, DC, for amicus curiae Pharmaceutical Research and Manufacturers of America. With him on the brief were Robert A. Long, Jr. and Christopher N. Sipes.

Steven P. Caltrider, Eli Lilly and Company, of Indianapolis, Indiana, for amicus curiae Eli Lilly and Company. With him on the brief were Robert A. Armitage and James J. Kelley.

Philip Allen Lacovara, Mayer Brown Rowe & Maw, of Washington, DC, for amicus curiae Washington Legal Foundation. With him on the brief were Donald M. Falk; and Michael O. Warnecke, Joseph A. Mahoney, and Thomas R. Stiebel, Mayer Brown Rowe & Maw, of Chicago, Illinois. Of counsel on the brief were Daniel J. Popeo and Richard Samp, Washington Legal Foundation, of Washington, DC.

Appealed from: United States District Court for the District of New Jersey

Judge Katherine S. Hayden

United States Court of Appeals for the Federal Circuit

03-1227, -1258

PFIZER INC.,

Plaintiff-Appellant,

v.

DR. REDDY'S LABORATORIES, LTD.
and DR. REDDY'S LABORATORIES, INC.,

Defendants-Appellees.

DECIDED: February 27, 2004

Before MAYER, Chief Judge, NEWMAN and LOURIE, Circuit Judges.

Opinion for the court filed by Circuit Judge NEWMAN. Dissenting opinion filed by Chief Judge MAYER.

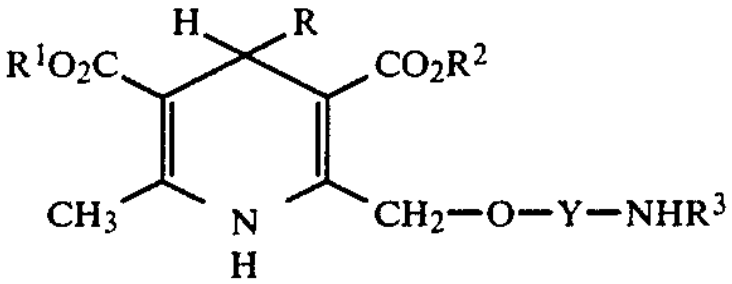
NEWMAN, Circuit Judge.

Pfizer Inc. appeals the judgment of the United States District Court for the District of New Jersey, ruling that defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (together "Dr. Reddy's") do not infringe the extended term of Pfizer's United States Patent No. 4,572,909 ("the '909 patent"), and on this ground dismissing the complaint.[1][1] We conclude not only that the extended patent term includes the claims that cover Dr. Reddy's product, but also that the dismissal was improperly granted. The judgment is reversed.

BACKGROUND

Pfizer is the owner of the '909 patent, which claims certain dihydropyridine compounds and their acid addition salts, including the compound having the common name amlodipine, and its salts. Amlodipine is the compound of claim 8. The relevant claims follow:

1. A dihydropyridine compound of the formula



or a pharmaceutically acceptable acid addition salt thereof, wherein Y is $C(CH_2)_2C$, $C(CH_2)_3C$, CCH_2 $CH(CH_3)C$ or $CCH_2C(CH_3)_2C$; R is aryl; R^1 and R^2 are each independently C_1CC_4 alkyl or 2-methoxyethyl; and R^3 is hydrogen, C_1CC_4 alkyl, 2-(C_1CC_4 alkoxy)ethyl, cyclopropylmethyl, benzyl, or $C(CH_2)_mCOR^4$ where m is

[1][1] Pfizer Inc. v. Dr. Reddy's Laboratories, Ltd., No. 02-02829, 2002 WL 3l833744 (D.N.J. Dec. 17, 2002).

1, 2 or 3 and R^4 is hydroxy, C_1CC_4 alkoxy or CNR^5R^6 where R^5 and R^6 are each independently hydrogen or C_1CC_4 alkyl; wherein aryl is phenyl; phenyl substituted by one or two of nitro, halo, C_1CC_4 alkyl, C_1CC_4 alkoxy, hydroxy, trifluoromethyl or cyano; 1-naphthyl; or 2-naphthyl.

7. A compound according to claim 1 wherein R is 2-chlorophenyl or 2,3-dichlorophenyl, R^1 is CH_3, R^2 is C_2H_5, Y is $C(CH_2)_2C$ and R^3 is H or CH_3.

8. A compound according to claim 7 wherein R is 2-chlorophenyl and R^3 is H.

Pfizer obtained federal registration of an anti-hypertensive, anti-ischemic drug product whose active ingredient is amlodipine, as the besylate salt. In obtaining the registration, Pfizer submitted clinical data obtained using both amlodipine besylate and amlodipine maleate. The besylate salt was selected by Pfizer for ease of tableting. The seventeen-year term of the '909 patent ended on February 25, 2003, but was extended for 1,252 days, until July 31, 2006, measured as a portion of the time consumed by the federal regulatory approval process, as authorized by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (the Hatch-Waxman Act), codified at portions of Title 35 and Title 21. Pfizer's expert declaration stated:

> In the Patent Certification section of the NDA for Norvasc® . . . Pfizer certified that "the drug, amlodipine, which is the subject of this application (NDA-19,787) and the formulation for such drug claimed by the listed patent (patent No. 4,572,909) provided in Section 14 of this NDA is the subject of the approval being sought under Section 505 of the Federal Food, Drug, and Cosmetic Act."

In Pfizer's application to the PTO requesting term extension under 35 U.S.C. §156, Pfizer identified Norvasc® as the product for which regulatory approval had been obtained, and stated that Norvasc® was "further identified" as amlodipine besylate.

In December 2001 Dr. Reddy's filed a new drug application, known as a "paper NDA" under 21 U.S.C. §355(b)(2), proposing to market amlodipine as the maleate salt, for the uses for which Pfizer had obtained federal approval, based on the data that Pfizer had provided to the Food & Drug Administration (FDA). Dr. Reddy's acknowledges that amlodipine maleate is covered by the claims of the '909 patent, but argues that the term extension applies only to the besylate salt because that is the registered product. The district court agreed with Dr. Reddy's.

DISCUSSION

The patent term restoration provision of the Hatch-Waxman Act is directed to new drug and medicinal products that are subject to pre-market federal regulatory approval. By restoring a portion of the patent term that is consumed during the approval phase, the incentive to develop and market products that require lengthy pre-marketing approval is intended to be preserved:

> The purpose of Title II [Patent Term Restoration] is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval. The incentive is the restoration of some of the time lost on patent life while the product is awaiting pre-market approval.

H.R. Rep. No. 98-857 at 15 (1984), reprinted in 1984 USCCAN 2647, 2670. The Hatch-Waxman Act balanced the term-extension benefit to patentees, with new benefits to generic producers. As discussed in Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1568 (Fed. Cir. 1997), the legislation was "designed to benefit makers of generic drugs, research-based pharmaceutical companies, and not incidently the public." See also Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 672 (1990). Balancing the Title II patent term extension benefit to patentees, Title I of the Act gave generic producers freedom from infringement during production and testing of generic counterparts intended to be sold after patent expiration. The Act also gave generic producers the right to rely on the patentee's data and approved uses to support approval of their generic counterparts, superceding the prior requirement that the generic product be independently shown to be safe and affective. See Id. at 672 (recognizing the equilibrium between the grant to generic producers of the right to use the patentee's data and conduct otherwise infringing activities, and the restoration of a portion of the time required for federal approval).

Dr. Reddy's application relied on the safety and efficacy data submitted to the FDA by Pfizer, which had included testing of amlodipine as both the maleate and besylate salts. Dr. Reddy's argues that Pfizer's term extension is limited to amlodipine as the besylate salt, and that amlodipine maleate is a different "active ingredient." Dr. Reddy's concedes that both products have the identical "active moiety," as it must in order to use Pfizer's approved registration. However, Dr. Reddy's argues that only the specific salt for which Pfizer obtained approval is protected by the extended term of the patent. In particular, Dr. Reddy's argues that the district court properly held that §156(b) limits the rights derived under the extended term of a patent to the specific form of the approved product, i.e., a free base or a specific salt, citing Merck & Co. v. Kessler, 80 F.3d 1543 (Fed. Cir. 1996), for support.

Pfizer argues that the patent term extension statute itself contemplated that a therapeutic product could be administered as a "salt or ester of the active ingredient," and that the extension is not defeated by simply changing the salt or ester. The codification states this scope:

> 35 U.S.C. §156(f) For purposes of this section:
>
> (1) The term "product" means:
>
> (A) A drug product.
>
> (B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.
>
> (2) The term "drug product" means the active ingredient of --
>
> (A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), or
>
> (B) a new animal drug . . .

> including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

The Food, Drug & Cosmetic Act similarly provides that a "drug product" includes any salt or ester of the active ingredient:

> 21 C.F.R. §60.3(b)(10) Human drug product means the active ingredient of a new drug or human biologic product (as those terms are used in the [FD&C] Act and the Public Health Service Act), including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

Pfizer stresses that the FDA's approval describes the approved product as "amlodipine." Dr. Reddy's stresses that in filing its request for term extension, Pfizer identified the approved product as amlodipine besylate.

The district court held that the term extension is limited to amlodipine besylate, and that although amlodipine maleate is covered by the claims, it is not subject to the extended term. The court reasoned that the statute limits the term extension to "the first permitted commercial marketing or use of the product," 35 U.S.C. §156(a)(5)(A), and that this was only for amlodipine besylate. Pfizer responds that the commercial marketing and use are the same for Dr. Reddy's salt form of amlodipine, and that 35 U.S.C. §156(f) makes clear that "drug product" means the active ingredient "including any salt or ester of the active ingredient." Pfizer points out that a changed salt does not affect the therapeutically active agent, which is the same amlodipine, whatever the salt. Pfizer argues that if a change in the salt removes amlodipine from the Hatch-Waxman Act's term extension benefit to the patentee, it also removes it from the Act's counterpart benefits to the generic producer.

We conclude that the active ingredient is amlodipine, and that it is the same whether administered as the besylate salt or the maleate salt. The statutory definition of "drug product" is met by amlodipine and its salts. Dr. Reddy's is proposing to market the "drug product," as defined in 35 U.S.C. §156(f), for the same approved uses. The statute foresaw variation in the salt or ester of an active ingredient, and guarded against the very loophole now urged. See 35 U.S.C. §156(f); 21 U.S.C. §355(j)(5)(D)(i) and (v). As several amici curiae point out,[2[2]] the Hatch-Waxman

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[2[2]] Amicus curiae briefs were filed by Eli Lilly & Co.; Merck & Co., Inc.;

Act established a balance whereby the patent term extension is offset by facilitating generic entry when the extended term expires, yet preserving the innovation incentive. Whether or not this bargain achieved "perfect symmetry" -- Dr. Reddy's argues that it was not intended to do so, but was designed to favor the generics -- the text of the statute shows that it was not intended to be defeated by simply changing the salt. None of the aspects offered to the district court or on this appeal suggests a statutory intent to provide the generic producer with access to the pioneer's approved uses and data while barring extension of patent coverage of the drug product whose approvals and data are provided. To the contrary, as we have discussed, the Hatch-Waxman Act foresaw and averted the potential loophole of a change in the salt of the active ingredient.

As we have observed, 35 U.S.C. §156(f) defines the drug product as including "any salt or ester of the active ingredient." See Abbott Laboratories, Inc. v. Young, 920 F.2d 984, 985-89 (D.C. Cir. 1990). The FDA ruled that "the term 'active ingredient' as used in the phrase 'active ingredient including any salt or ester of the active ingredient' means active moiety." Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,358 (F.D.A. Oct. 3, 1994). The FDA has defined "active moiety" as "the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . responsible for the physiological or pharmacological action of the drug substance." 21 C.F.R. §314.108(a).

The district court misconstrued the statute, in holding that the extended patent term did not cover any amlodipine salts except the besylate. The Act by its terms extended the term of the patent for the registered uses of the drug product including its salt esters. The "rights derived" provision of §156(b) specifically limits the extension to "any use approved for the product," which means that other, e.g., non-pharmaceutical uses, are not subject to the extension. That provision does not contain any limitation regarding the form of the product subject to the extension. In fact, §156(f) clearly provides otherwise, in defining the term "product" as "including any salt or ester of the active ingredient." Thus, Dr. Reddy's attempt to limit the extension to the specific approved salt on the basis of the "rights derived" provision of

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Wyeth; Pharmaceutical Research & Manufacturers of America; Takeda Chemical Industries, Inc.; and Washington Legal Foundation.

§156(b) to the approved product is unsound. The district court's reliance on Merck, 80 F.3d 1543, is inappropriate, for the issue of that case is unrelated to that before the district court. The issue in Merck was whether a patent whose term at the time of grant was 17-years-from-grant, and whose term had duly been extended under §156, could obtain a second extension after the 20-years-from-filing term became available to that patent. The court in Merck held that a second extension was not available. The Merck case is not relevant.

We conclude that the extended term of the '909 patent covers amlodipine and any salt or ester, as provided by §156(f) and as claimed in claims 1, 7, and 8. The extension is not limited to the besylate salt of amlodipine. The judgment of non-infringement and ensuing dismissal, is reversed.

REVERSED

United States Court of Appeals for the Federal Circuit

03-1227, -1258

PFIZER INC.,

Plaintiff-Appellant,

v.

DR. REDDY'S LABORATORIES, LTD.
and DR. REDDY'S LABORATORIES, INC.,

Defendants-Appellees.

MAYER, Chief Judge, dissenting.

Because I believe the district court correctly interpreted 35 U.S.C. § 156(b) to limit the patent term to the specific product that was the subject of Food and Drug Administration approval, I dissent. As the court points out, section 156(f) defines a product as a new drug "including any salt or ester of the active ingredient." What the court fails to consider, however, is that regardless of how a product is defined in section 156(f), to be eligible for a patent term extension, that product must "ha[ve] been subject to a regulatory review period before its commercial marketing or use." 35 U.S.C. § 156(a)(4). In this case, the product that was subject to regulatory review was amlodipine besylate. It was not merely amlodipine, nor was it amlodipine maleate, the product that Dr. Reddy's seeks approval to market. As

such, the product amlodipine maleate cannot qualify for a patent term extension; it does not comport with the statutory requirements for eligibility.

An extension also does not comport with precedent. In Merck v. Kessler, 80 F.3d 1543, 1547 (Fed. Cir. 1996), we held that a patent can be given only one extension regardless of the number of drugs that it may claim were subject to approval. And, in interpreting section 156(b)(1), the section at issue in this appeal, we held that "the restoration period of the patent does not extend to all products protected by the patent but only to the product on which the extension was based." In this case, the restoration period should apply narrowly to cover only amlodipine besylate.

四、律師訪談內容

欲了解美國學名藥廠採用何種方式挑戰專利以進行訴訟，來作為與專利藥廠的競爭手段，我們選擇數家法律事務所的律師作為訪談對象。訪談的內容主要分成二個方向：第一是由法律事務所的角度而言，學名藥廠在於進行挑戰 paragraph IV 專利訴訟前的準備，有效的專利訴訟之競爭策略為何、以及學名藥廠是否有更積極的方式來挑戰專利藥廠；第二個方向則是關於 anti-trust 議題，針對日前的專利藥廠與學名藥廠於申請 FDA 審理藥品許可時，專利藥廠已不像過去以訴訟方式來解決與學名藥廠的紛爭，而是與學名藥廠直接進行和解的方式來解決競爭問題，以及有些專利藥廠直接設立學名藥廠，或是以併購學名藥廠的作法來減少學名藥之競爭，以維持原本專利藥品的利潤，此作法與 Hatch & Waxman Act 的設立原意互相抵觸，是否會引發其他與 anti-trust 相關的問題，而使得挑戰 paragraph IV 政策失去鼓勵研發以及鼓勵學名藥發展的實際效用？以下則是列出各家法律事務所之訪談記錄。

(一) Finnegan, Henderson, Farabow, Garrett & Dunner LLP

受訪時間：Jul 13, 2007，受訪人員：John R. Alison

1. 學名藥廠挑戰專利藥廠之方式

(1)Paragraph IV :

依據 Hatch & Waxman Act 中，為排除專利侵權的疑慮，在學名藥廠提出 ANDA 的申請時，必須證明欲申請之藥品並無侵犯同成份藥品的專利，而同成份藥品的專利資訊則是登錄於所謂「橘皮書」(Orange Book)上。因此學名藥廠必須提出以下四種證明之一，來說明其欲申請之藥品並無專利侵權的疑慮：所謂的四種證明即是：paragraph I 欲申請之學名藥並未有任何專利登錄於橘皮書中、paragraph II 雖有專利登錄於橘皮書，但專利已經過期、paragraph III 雖有專利登錄於橘皮書，但該專利即將到期，而學名藥廠會於該專利到期後再銷售學名藥、paragraph IV 雖有專利登錄於橘皮書中，但此一專利無效；或學名藥廠所申請 ANDA 藥品，並無侵害已登錄的專利權。由於前三種情況不是無專利權、專利權過期，就是學名藥廠將會等待其專利權過期，並不會有專利侵害的疑慮。當學名藥廠可以舉發專利藥廠的專利無效，或是學名藥廠可以舉證自己的產品並沒有侵害專利權時，即可提出 ANDA 的申請。在學名藥廠提出申請的同時，亦要通

知專利藥廠其專利無效或是沒有侵害專利的事實，專利藥廠則可在接獲通知後 45 日之內提出專利侵權訴訟，除了可以中斷 FDA 的審查程序 30 個月外，亦可以針對學名藥廠藥品是否有專利侵害於法院中做出判決，此即是所謂的 paragraph IV patent challenge。

(2)Reexamination :

時間花費較長，但費用較便宜。再審查程序又可以分成二種，Ex parte Reexamination 以及 Inter parte Reexamination。Ex parte Reexamination 為較早之前即已施行之再審查程序，此為單方再審查程序，適用的範圍包括所有已公告並取得專利權之案件，任何人均可針對已公告專利的任一個申請專利範圍提出再審查程序的請求，且可針對同一個專利的不同內容提出數個 Ex parte reexamination 的請求。由於任何人(包含專利權人在內)在該專利的專利權期間內，均可將可能影響專利有效性的前案資料(prior art)以書面提交方式給予美國專利局，所提出之再審查必須採用書面方式來進行。單方再審查程序的缺點即是，提出再審查程序的申請人無法參與後續答辯及申復，僅有專利權人可針對內容提出答辯，因此可能無法使專利案範圍得到最佳溝通與了解。但此單方再審查程序亦有其優點，申請人之前已提出之前案資料可再度於訴訟案中，作為該專利缺乏新穎性、實用性、或顯而易見性等可作為駁回專利權之證據。而 Inter parte reexamination 則是提出申請再審查程序之申請人，可以針對專利權人所答辯之內容進行申復及答辯，因此可在 inter parte reexamination 時雙方即可針對專利範圍進行溝通及了解，也因為如何，進行 inter parte reexamination 之提出證據並不能使用於後續的專利訴訟中。也因為任何人均可提出再審查之程序，因此專利權人亦可能依此程序來進行再次確認其專利權強度之方法。

(3)Reissue :

時間需花費多久較不確定，針對 Reissue 之再公告之專利，由於所有的人都可以提出再公告之要求，因此此程序未必是非專利權人、或是欲挑戰專利權之競爭者會提出再公告程序，在多數的情況中，專利權人亦可以提出再公告之要求。專利權人提出再公告程序的目的，與競爭者提出再公告程序的目的並不同，再公告的程序中，專利權人可以將其已取得之專利權利範圍進行修正，可以將已揭露之專利說明書中未取得之專利範圍，再行加入再公告之權利範圍申請。亦即，在進行再公告之程序中，專利權人是可以修改其權利範圍內容，但其權利範圍是否真能擴大或是僅能限縮，則需

要視其專利說明書是否可以同時支持其權利內容。進行專利再公告的另一個好處則是專利權人可再度的確認其專利權的強度，使其專利更不容易被挑戰成功。對於擁有專利權的專利藥廠而言，若是先進行再公告程序時，而取得以 RE 為首之專利號時，則無異更加強其專利強度，使其競爭者更不易以專利權無效之訴來提起訴訟。如此的話，對於學名藥廠而言，此類已進行過再公告之專利，其先前技術是較難取得的，因此若以突破其專利，或是以迴避專利的方式進行研發則是較有助益的。

2. 做好 Due diligence 最重要

(1) 可觀察對方多久完成 prosecution。
(2) 該藥品有沒有 benefit 可以 cover 所有開支之費用。
(3) 可尋求 second opinion。

3. 案例建議：

前兩天 Federal Circuit 剛好有兩個案與 Hatch-Waxman Act 相關，可以參考。參訪公司建議：針對於劑型開發的公司，其不但可以完美迴避專利藥廠的專利，且不會受到訴訟的痛苦，因此會是學名藥廠的較佳競爭方式，因此在東岸的 Mylan，以及在西岸的 Waston 及 Impax 亦是非常好的參訪公司，其中 Impax 的劑型開發算是較為有名的，不但可以對抗專利藥廠，亦使別人無法進入其藥品市場。

4. 其他

(1) 有登錄在 Orange Book 之專利藥廠才能擁有 30 天中止 FDA 審查學名藥證之權利。
(2) 學名藥廠先前小心選擇標的最重要。
(3) 學名藥廠事前先準備再出擊可以降低自己的律師費用。
(4) 研發初期先做好內部 examination 過幾年後再做外部 examination。

5. Hatch-Waxman Act 法案的設計是否造成鼓勵專利訴訟的結果?

在 Hatch-Waxman Act 中，國會並沒有要鼓勵或是抑制專利藥廠或是學名藥廠的訴訟產生。國會只是希望能站在公眾利益立場的角度去設計這樣的法案。在原始的法律架構下，屬於專利權人的專利藥廠是有權利去排除學名藥廠在專利到期前的任何先進行之為符合 FDA 要求之試驗行為。如果是原本法律的設計下，專利法將會使學名藥進入市場的速度在專利過期後還需要延遲數年的時日，無法直接進入市場與專利藥品作競爭。另一方

面，國會亦創造一安全港的專利侵權免責例外條文，即 safe harbor of 35 USC 271(e)，為了穩定醫藥產品的市場，國會需要創立一個針對與專利權競爭之清楚且單一的方式及法案來讓大家遵守並執行。事實上，國會設計對於學名藥廠及專利藥廠都具有鼓勵性的方式來促使學名藥可以迅速進入醫藥市場，同時為鼓勵發明者，亦提供增大的專利穩定性及可預測性於有專利所保護之藥品的醫藥市場。也許有人會認為 Hatch Waxman Act 使得許多挑戰專利的學名藥廠出現，且對於學名藥廠是一種利多的法案，但在醫藥產業的巨額利潤中，特殊的醫藥組合物可能創造非常大量的經濟價值以鼓勵大家去競爭此市場。而以權利為導向的經濟中，如此的鼓勵方式，則會造成許多專利的挑戰者。

(二) Nixon Peabody LLP

受訪時間：Jul 16, 2007，受訪人員：Lawrence M. Sung J.D. PhD

1. 學名藥廠如何選擇專利藥廠的藥品來進行專利挑戰?

學名藥廠會針對較容易攻擊之藥品做研發，應先針對其 orange book 上所列出來之專利作分析，取得其 file wrapper，針對其專利申請時所放棄之範圍及可能相關的前案作分析，以確定是否能進行 design around 的程序，以迴避其專利。

2. 如果是化合物的代謝產品的專利，那應該如何克服?

首先應視其是否可取得專利，是否符合可專利的要件，如果不是的話，可採用舉發程序將其專利舉發。如果是藥品代謝中一定會產生的代謝產物之一的話，那麼就非常不容易閃躲。

3. Hatch-Waxman Act 法案的設計是否造成鼓勵專利訴訟的結果?

Hatch-Waxman Act 法案為了使學名藥製造商可合理在專利到期日之前先進行研發活動，然後專利藥廠亦可以據此向學名藥廠提出 ANDA 申請時一併提出告訴。由於向學名藥廠提出告訴的行為可以凍結 FDA 針對該藥品的許可證申請長達 30 個月的時間，因此專利藥廠很少會放棄向學名藥廠提出告訴的機會。因此對於學名藥廠而言，是無法避免訴訟的過程及花費的。但學名藥廠可將藥品設計成可以達到生物相等性(bioequivalent)，同時亦不會有專利侵權的問題的藥品，如此則可以降低訴訟的費用。進行這樣的研發之前可以經由分析專利範圍之後，針對以下部份作迴避，例如文

義侵害的部份、專利範圍的均等性(the doctrine of equivalents)、專利申請過程中未敘明的元件、禁反言(prosecution history estoppel)的部份。如此的方式可鼓勵和解、引起撤銷告訴(dismissal)、或是產生提前判決(summary judgment)，不過，專利藥廠還是有上訴的權利。

4. 在此類的專利訴訟案中，是否對專利藥廠比較有利，還是對學名藥廠比較有利?

我並無相關的統計資料來分析是針對此類訴訟中是學名藥廠較有利或是專利藥廠，但是有一些法院對於專利藥廠是比較有利的，例如：District of New Jersey, Southern District of New York, Eastern District of Pennsylvania, and Northern District of Illinois，因為多數的專利藥廠是位於這些州裡的，因此如果是學名藥廠的話，可能的話，應迴避這些法院。

5. 除了與 FDA 審查有關之 Paragraph IV certification 的專利訴訟之外，專利藥廠未必會把所有的專利列於 Orange book 上，是否有其他可能造成訴訟?

在 Paragraph IV certification 時，是不具有對人的審判權之民事糾紛(personal jurisdiction controversy)，而申請 ANDA 的程序即是提出侵權的行為。如果 ANDA 的訴訟沒有解決訴訟的爭端，或是專利藥廠沒有提出訴訟時，訴訟案件還是有可能在學名藥廠進行運輸或銷售時被提出，可由 ITC(International Trade Commission)在地方法院中提出對物的管轄權來提出訴訟。

6. 對於近來有專利藥廠併購學名藥廠的商業行為，是否有 anti-trust 的問題產生?

針對專利藥廠與學名藥廠之間的合併 Mergers、購買 acquisitions 以及和解 settlement，FTC 及 DOJ 都會針對是否有造成 anti-trust 的議題作重新檢討。主要檢討的重點在於是否有影響到市場力量以及是否有共謀行為(collusive behavior)的證據。當然在於專利藥廠付權利金(reverse payments)給學名藥廠的行為中，亦可能造成 FTC 及 DOJ 更多更仔細的監控。至於 Schering Plough 案中，由於雙方和解的約定為學名藥廠延後上市，但學名藥廠的產品上市時間還是早於專利逾期的期限，因此 CAFC 判此案件並未違反 antitrust，是否在日後只要不延長專利藥廠原有之專利期即不算違法 antitrust 呢，雖然目前 CAFC 的看法是如此，且最高法院已決定不接受本案上訴，但並不表示允許專利藥廠與學名藥廠的和解要求是，學名藥廠上

市時間在專利逾期之前即不算違法。還是需要依照個案判定，FTC 及 DOJ 還是會以公眾利益作為考量點來作評估。FTC 會先篩選過所有專利藥廠與學名藥廠和解的案件，若該藥品整體市場大小即影響非常巨大時，即會確定進行調查。但若是專利藥廠，如 Novatis 併購了學名藥廠 Sandoz 時，目前尚未有若當 Novatis 之專利即將逾期前 Sansoz 申請 Paragraph IV，且 Novatis 不提出訴訟的此類案例，但 FTC 依然會調查此類行為是否有違反 Antitrust 的實質。

7. 關於 Merck v. Integra 案中，您是否有其他的看法?

Merck v. Integra 案中是針對多個研究工具的專利是否符合試驗免責的標的。如果研究工具專利在診斷及臨床試驗上具有非常大的使用度時，則非常可能會落入專利法第 271(e)(1)的試驗免責條款中，而使得侵權的人可能免除其侵權的責任。對於研究工具專利的專利權人而言，則可能改變其商業模式，使得未來未必會有人願意研發研究工具專利，或是以營業秘密的方式來保護其研究工具之技術。

(三) Bingham McCutchen

受訪時間：Jul 23, 2007，受訪人員：Gary M. Hnath

1. 337 有關藥廠的案例?

事實上並不多，僅有一個仿冒 Viagra 之案例較為相關。

2. Hatch-Waxman Act 法案的設計是否造成鼓勵專利訴訟的結果?

我會說 Hatch Waxman act 並不會鼓勵專利，因為此法案的重點是在於使學名藥廠可以將其產品合法的推到市場上作銷售的一個程序。學名藥廠需要去考慮產品是否可成功迴避專利，以及訴訟的可能成本。這些訴訟花費非常高昂，而專利藥廠是絕對會為了保護其市場領導地位而非常努力的投入訴訟的抗爭中。也因為其風險非常高，同時當成功戰勝每個案子時，其回饋亦非常高。因此為迴避這些可能風險、取得高額報酬的代價即是需要非常小心的投入相當大心力於了解各個欲研發的產品之專利內容。第一家挑戰專利成功的學名藥廠則會得到一段時期的獨家銷售權，其獨家銷售權的價值特別高。若專利藥廠被學名藥廠以 Paragraph IV 挑戰後，並沒有提出訴訟的話，學名藥廠一樣可以擁有 180 天之獨賣期，因此學名藥廠的獨家

180 天之收益頗豐。而另一個需要考慮的點則是在於學名藥的專利期及獨家銷售期到期之後，其價格會下降的非常迅速，這點亦需要考慮在內。

3. 在此類的專利訴訟案中，是否對專利藥廠比較有利，還是對學名藥廠比較有利?

學名藥如果有許多的競爭時，亦會增加其風險程度。通常十家挑戰者可能只有一家會成功，當然成功的那一家學名藥廠所獲得的回饋亦是非常高昂的，因此其在訴訟上的花費如此之高亦是情有可原的。

4. 學名藥廠是否有其他更積極的方法來對抗專利藥廠?

不同的解決之道總是會存在的。除了與其直接以專利訴訟方式競爭之外，如果競爭的內容過於強烈時，專利藥廠亦會想辦法來進行和解程序。但如果為了要保護住原有的市場時，則比較難以和解的方式來進行取回市場的方式。

(四) Patton Boggs LLP

受訪時間：Jul 24, 2007，受訪人員：Scott A.M. Chambers, Therese M. Finan

1. Hatch-Waxman Act 法案的設計是否造成鼓勵專利訴訟的結果?

對於這點，我並未覺得此法案的設計在實質上有鼓勵訴訟的做法，最主要的目的是在於使學名藥在真正上市之後可能產生的訴訟提早到學名藥上市之前。此法案對於學名藥廠在市場上的存活性非常重要。通常專利藥廠對於藥品的訂價非常高昂，但學名藥的訂價非常低。舉例而言，專利藥廠的一顆藥丸可能製造成本是 0.05 元，但是售價是 1 元，而其利潤高達 0.95 元，但是學名藥廠的同樣一顆藥丸的製造成本也是 0.05 元，但是其售價只有 0.1 元，其利潤只有 0.05 元。如果專利藥廠要等到學名藥廠開始銷售其學名藥之後再來提出專利侵權的告訴，而訴訟結果在數年之後才有判決出現，而當專利藥廠贏得專利訴訟後，向學名藥廠要求巨額賠價，要求學名藥廠付出專利藥廠可能之所失利益時，所失去之利潤是專利藥才能銷售到的高額價格，而不是學名藥廠。這樣的話，如果學名藥廠一旦輸掉官司時，則非常可能造成學名藥廠的破產。而在 Hatch & Waxman 法案中，學名藥廠可以先確定其藥品是沒有侵權的問題，不需要將整個公司的未來壓寶在一個被訴訟的產品上。對於專利藥廠而言，並不是件容易達到談和解的結果，因為專利藥廠的利潤範圍太大了，以致於專利藥廠不需其他相同

廠商進入這個市場。如果一個學名藥廠打算與專利藥廠進行訴訟的話，其訴訟費用約需先行準備 4-6 百萬元。除了金錢之外，尚需準備如何將專利藥廠的專利進行舉發程序的相關證據。

2. 訴訟費用如此之高，學名藥廠是否有其他的方式來與專利藥廠作競爭?

雖然訴訟費用非常昂貴，但是對於勝利的一方而言，其所獲得的利益非常之大。有時專利藥廠甚至會把其專利授權給學名藥廠，尤其當其覺得自己的專利保護性不夠大或是其專利非常容易受到挑戰成功時，則會考慮將專利授權或是與學名藥廠談和解事宜。不過，目前這樣的情況，可能會有 antitrust 的問題，可能會造成 FTC 及 DOJ 的特別關注。

3. 在此類的專利訴訟案中，是否對專利藥廠比較有利，還是對學名藥廠比較有利?

學名藥廠很少會被起訴(DJ jurisdiction)。而在於專利藥廠而言，選擇較有利的法院是異常重要的一環。專利藥廠喜歡選擇需要把專利訴訟進行非常久之法院，尤其是訴訟的期間會大於 30 個月的法院，其原因則是因為 Hatch & Waxman 法案最多可要求 FDA 停止審理長達 30 個月。相反的，在學名藥廠的立場則是希望減少訴訟的時間，尤其像在是一些所謂"rocket docket" 的法院，進行的愈快速的法院，對於學名藥廠的好處愈多。

4. 是否有其他方式來挑戰 paragraph IV 之專利?

我對於此題目並不完全理解，不過，對於 ANDA 所需要的資料，最重要的是產品的安全性跟有效性，才能取得與專利藥品等效之藥品許可證。除了 paragraph IV 是說明專利是否無效或是產品是否沒有侵權的疑慮之外，學名藥廠也可以主張其產品沒有專利、或是專利已經過期等等的方式，即 paragraph I, paragraph II。

5. 對於近來有專利藥廠併購學名藥廠的商業行為，是否有 anti-trust 的問題產生?

Anri-trust 是一個主要需要考慮的議題，但這個議題正在慢慢成型中。專利藥廠及學名藥廠目前都同時遇到這個問題，如果被發現到有涉及不正競爭或是共謀行為時，則可能會有三倍的損害賠償問題產生。而在於專利藥廠併購學名藥廠的商業行為中，雖然並不是一個非常嚴重的問題，但是目前 FTC 及 DOJ 正在討論這些議題中，也許在近期即會有答案。

6. 針對 CREATE Act 是否對於專利藥廠及學名藥廠有一些不同的影響?

Create Act 對於專利藥廠而言是非常有利的一個法案,但對於學名藥廠的好處則是有限制的。根據 Create Act 法案所述,專利藥廠可以與大學或是其他研究單位擁有長期之研究計畫的合作及研發合約,因此而取得非常便宜的早期研發成果。此法案同時亦允許合作者可取得較狹窄的發明內容(narrow discoveries)即可以進行較廣泛的專利保護之申請,如此的作為則可以在早期即把其他人可能造成的競爭阻擋於外。至於 Merck v. Integra 的個案中,在訴訟結果出爐之後,Integra 的研究工具專利在醫藥產業的價值被貶低不少。也許透過立法的方式可以解決這樣的問題,但我不認為專利藥廠會放棄這麼有價值且不需要高花費的方式來與大學合作的權利,尤其大學通常是擁有研究工具專利的專利權人。

(五)小結

針對美國學名藥廠應如何進行專利訴訟的準備,首先應針對橘皮書之專利作分析及拆解,可採用二個方式:一、做橘皮書上所列的專利無效,包括:a. 舉發專利無效(Invalidation)、b. 再審查程序(Reexamination)、c. 再公告程序(Reissue)。二、迴避其專利申請範圍。

如何使橘皮書上所列的專利無效? 美國的專利舉發程序,可以分為司法及行政雙軌制程序。所謂的司法體系則是舉發人向聯邦地院訴請專利無效,若有不服聯邦地院判決時,則可再上訴於聯邦巡迴上訴法院(CAFC)。行政體系則是舉發人向 USPTO 提出專利無效的申請,舉發人可以採用數種方式提出專利無效,主要的證據可由其專利申請歷史(file wrapper)中著手,例如提出在專利優先權日之前的可能相似或相同之先前技術(prior art)以舉發其專利缺乏新穎性(Novelty, 35 USC 102[3]),或是提出專利案不具有產業利用性(Utility, 35 USC 101[4]),或是可輕易由其他之先前技術組合而成的發明,而缺乏專利的基本要件:非顯而易見性(Non-obviousness, 35 USC 103[5]),亦可以提出其不具有法定不予專利標的或不符合專利說明書的完整揭露要件或記載不實(35 USC 112[6])的理由,或是無法據以實施(un-enablement)其專利說明書的內容,或是發明人記錄不實等等方法,以上種種內容均可以作為向法院或是美國智慧財產局舉發其專利無效之舉發要件。舉證

[3] 35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.
[4] 35 U.S.C. 101 Inventions patentable. Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
[5] 35 U.S.C. 103 Conditions for patentability; non-obvious subject matter.
[6] 35 U.S.C. 112 Specification.

之資料並無嚴格的限制，舉發的成敗是在於其證據力的強弱，因此，如能找出比申請案更早出現的先前技術，則是最佳可以使專利撤銷的理由。一旦專利權經確定撤銷後，專利權之效力視為自始不存在，則專利訴訟亦無法成立了。除了撤銷其專利之外，亦可經由行政程序之美國智慧財產局之再審查程序及再公告程序來將其專利範圍修正，此程序之好處即是可經由行政程序即決定其專利權是否存續，但此再審查及再公告程序亦常是專利藥廠用以證明其專利強度的一種方式，因此對於此類專利則需以迴避專利或是突破專利的方式作為競爭策略，而非以舉發專利無效之方式來競爭。

至於如何迴避其專利申請範圍？進行這樣的研發之前，可以經由分析專利範圍及分析其專利申請歷史(file wrapper)中著手，針對以下部份作迴避，例如文義侵害的部份、專利範圍的均等性(the doctrine of equivalents)、專利申請過程中未敘明的元件、禁反言(prosecution history estoppel)的部份來進行研發。由於學名藥廠要針對其化合物專利進行突破，並非容易的事，而且，如果把化合物專利進行舉發的話，其他的學名藥廠亦會跟進，因為化合物專利如果被舉發之後，其專利權即自始不存在，故其亦不可能造成其他藥廠的進入障礙。因此學名藥廠較佳的作法其實是在迴避專利藥廠的專利之外，還可以產生一些新的專利來保護自己的產品，例如使用不同的劑型專利來保護，如果專利藥廠的原本產品是注射的劑型，則學名藥廠可以採用口服的劑型來創造障礙，同時也不會有專利侵權的疑慮，同時也可以阻礙其他的藥廠進入這個相同產品的市場。

五、藥廠訪談內容與參觀心得

訪談學名藥廠的內容部分，最主要分成二個方向來了解其智慧財產管理方式，以及專利訴訟的策略；在於智慧財產管理方式所希望了解的部分包括智慧財產部份的組織運作、如何鼓勵研發、如何選擇研發標的、以及智慧財產之產出及管理方式；而在於專利訴訟的策略方面，則是包括如何準備挑戰 paragraph IV、是否有其他更積極防禦或攻擊的方式，另外亦討論到對於專利藥廠直接設立學名藥廠，或是 merge 學名藥廠的作法是否會直接影響其公司的競爭策略，以及對於現行法規的具體建議等等議題。

因此依據以上之詢問方向，透過 MMOT 學員柯麗娜小姐的安排，拜訪 Impax Laboratories, Inc.之許中強總經理。許中強博士**(Larry Hsu)**於 2007 年 8 月 7 日接受本小組一小時十分鐘的訪談，其於訪談全程中非常詳細的回答每個提問，並且也安排我們參觀他的藥廠生產流程，得到非常寶貴的資訊與經驗，特此非常謝謝許總經理及柯小姐，以下是其公司簡介及訪台紀錄。

(一)公司簡介

1. 公司歷史

1999 年 12 月 14 日 reverse merge：Global Pharmaceutical Corporation + Impax Pharmaceuticals, Inc. = Impax Lab.

(1) Global Pharmaceutical Corporation : sales, marketing, distribution

(2) Impax Pharmaceuticals, Inc. : research, development

2. 公司主要產品方向類別

(1)Generic drugs (Global Division)

a.策略

(a)Speed to filing

(b)Legal strategy

b.方向

(a)Controlled-release generics

(b)Niche generic products : 例如難以尋找 API 來源、複雜的 formulation or development、special handling requirements

(2)Branded drugs (Impax Division) : Central nervous system disorders

a.公司廠址

(a)Headquarter : Hayward California，R&D facility, commercial manufacturing

(b)Philadelphia : administration building, warehouse, commercial center

b.2003 年年報

(a)9 ANDA approvals received (7 final, 2 tentative)

(b)8 new applications filed (2 IND)

(c)Revenue : US$ 58,818,000 (比 2002 年增加 139%)

c.對外合作情形

(a)Teva 子公司(2001 年 6 月)

共合作 12 項藥品，Impax 擁有美國獨家 marketing right 以及北美、南美、歐洲、以色列之優先 option 權利，已知之 6 項 Impax 通過 FDA 之藥品包括：

(i)Laratadine / Pseudophedrine Sulfate 12-hr Extended Release Tablet (generic of Claritin D 12-Hour)

(ii)Laratadine / Pseudophedrine Sulfate 24-hr Extended Release Tablet (generic of Claritin D 24-Hour)

(iii)Loratadine Orally Disintegrating Tablet

(iv)Bupropion Extended Release Tablet (generic of Wellbutrin SR Tablet)

(v)Bupropion Extended Release Tablet (generic of Zyban Tablet)

(vi)Omeprazde Delayed Release Capsule (generic of Prilosec Capsule)

(b)Novartis (2001 年 12 月)

Loratadine

Impax 開發與生產、Novartis marketing and sales

(c)Wyeth (2002 年 6 月) 品牌名為 Alavert

(i)Laratadine / Pseudophedrine Sulfate 12-hr Extended Release Tablet (generic of Claritin D 12-Hour)

(ii)Laratadine / Pseudophedrine Sulfate 24-hr Extended Release Tablet (generic of Claritin D 24-Hour)

d.Impax 開發與生產、Wyeth marketing and sales

(a)Schering-Plough (2002 年 6 月)：Laratadine / Pseudophedrine Sulfate 12-hr Extended Release Tablet (generic of Claritin D 12-Hour)

(b)Leiner Health Products (2004 年 7 月)

(i)Laratadine / Pseudophedrine Sulfate 24-hr Extended Release Tablet (generic of Claritin D 24-Hour)

(ii)Loratadine Orally Disintegrating Tablet

(二)總經理訪談記錄

1.公司歷史

(1)當年希望能找一家"殼"來 IPO 因此 merge 了已上市的 Global 形成了現在的 Impax Lab.。

(2)目前共有 10 棟建築，8 棟位於總部 2 棟位於費城。策略是不花錢購買房地產，除了 R&D 以及生產部分之廠區(4 棟)為購買的(包括保留當年在加州的 Impax 現址以及位於費城之 Global 現址)，其餘均為租賃。

2.組織架構

(1)公司員工：共約 700 人，其中 R&D 約為 150 人。

(2)區分為三大部門

a.Brand Development： 共約 80 人，分為 R&D 以及 sales force

(a)R&D： 共約 20 人，包括臨床以及法規人員。

(b)Sales force： 共約 66 人，專攻 CNS 領域，目前銷售別家廠牌之藥品用以 cover 本單位之費用並賺取一小部份的收入。

b. Generic Development：

(a)R&D： 共約 120 人。

(b)Sales marketing： 共 5 人。

c. Administration： 包括 finance, legal (共 4 位 in house), IT 等 Legal 部門負責 IP management；訴訟的部分每年 legal fee 美金千萬以上。

(3)所有之生產於總部進行，再運抵費城進行包裝(顧客大多在東岸)。

(4)Generic 部門的 R&D 經費多過 branded 部門之 2 倍多。

3.公司產品

(1)以技術導向之 controlled release generic 為主，此領域之實際 ANDA 擁有張數目前居冠(領先於 Teva)。

(2)2002 年開始 branded 藥品之發展。

a. 只做 CNS 領域(許總先前就在 CNS 領域工作)。

b. 目前第一個藥品正在等待 FDA 之通過(預計明年初可通過)，此藥品針

對 Parkinson。

c. 由於資金有限，因此一次僅進行一個藥品之發展，且效率迅速。

d. 第二個藥品正在進行臨床，預計於明年送 FDA 審查。

4.市場狀況

(1)Generic 與 branded 之市場狀況：由於 branded 之 pipeline 日趨下降，為保護市場，branded 努力做 line extension。

(2)Branded 之策略做法除了專利訴訟外，還利用 citizen petition (例如要求 FDA 該藥品不能只進行 BE 試驗，必須要重新審查等)來拖時間(至少可拖一年)。

(3)目前單一訴訟的平均 legal fee 為 US$ 500-600 萬左右(依專利數量與 claims 數量而有所調整)。

(4)不建議台灣藥廠繼續做一般之 generic 而應該做 super generic，理由如下：

a. 台灣公司目前均無經費打訴訟。

b. 印度以及大陸的競爭對手強，除非做 controlled-release(但是現在越來越多公司在做這方面)。(印度藥廠之 R&D 人數平均共 1,500-2,000 人，平均薪資為 US$ 1,000)

(5)知道永信做了幾年的新藥而東洋則沒有做而是著重於 dosage form，認為東洋的做法是對的，但也知道永信的經費充足且業務能力強。

(6)過去幾年台灣的藥業並沒有成長。

5.公司策略與決策流程

(1)Formulation 之發展：

a. Alza 之方式：有了 idea 後進行 dosage form 之發展，再拿出來賣掉，此方式許總也做過，知道非常的辛苦，且 R&D 很花錢，10 個產品中僅有 1 個會成功(沒錢)。

b. Imapx 之方式：先找出目標產品，再做技術開發，且不愛 license。

(2)決策流程：

a. Marketing Planning：此為非常重要之團隊(generic 以及 branded 部門各有自己的團隊)，放於 R&D 以及 sales marketing 部門之間，主要為

科學家轉而進行 business marketing。此團隊成員包括 R&D、marketing 以及 legal，共約 5-6 人。

b. 團隊先 identify 目標產品→amend need→literature 查詢→PK 人員確認有無發展之可能性→團隊將目標以及理由交由總經理決策→R&D 正式進行開發；此流程可預估出未來該產品發展之長相。

c. Compound patent 不碰，其他的均可，不怕打訴訟。

d. 專利逾期前 5-7 年即開始做，時間點之選擇極為重要，太早或太晚都不行。

(3)IP management 極為重要且嚴格，目前將於台灣設立的廠區，並不會在台灣上市產品，目標還是美國市場所以才設廠於台灣(若市場目標是台灣，廠區將會設在大陸)，相關 IP 管理還是由總公司來進行。

6.Hatch-Waxman Act 之相關討論

(1)從 generic 的角度來看，HWA 之助益極大，但從 1984 年至今已多年確實有許多的漏洞，因此 3 年前 MMA 有修改以補一些漏洞。

(2)唯 citizen petition 這塊很難補，不論是個人或是公司均可提出。

(3)Authorized generic 之問題：得到 180 獨賣期的學名藥廠並非真正的獨家，branded 藥廠可以授權給其他家學名藥廠，換個品牌之後一樣可以直接進入市場，不受 180 獨賣期之影響(不受 FDA 管制)，此極為不應該之情形。Congress 已經討論過好幾次，但由於 branded 藥廠在 Congress 之勢力龐大，目前並無結果。

(4)針對 branded 藥廠併購 generic 藥廠的情形，並無怨言，僅要求法律公平即可(Impax 自己也做 branded)。

(5)針對 branded 未將其專利放入 Orange Book 之可能情形：

a. 漏放：branded 通常會與已放入 Orange Book 之專利一起控告，以爭取 30-month stay。

b. 沒放：等 generic 上市之後才告(一直不告的反而麻煩)。

c. Declaratory Judgment (DJ)：之前法院並不接受此申請，近幾個月才有 1-2 個受理的情形，也就是 generic 去向法院申請要求 branded 要嘛就現在訴訟，不然以後就不能再提告；法院受理此之情況認為並不合理。

(6)Paragraph IV：此申請在於 generic 表示並不侵權或是該專利無效(此部分要提出很多證明)。Impax 申請過很多的 Paragraph IV，目前僅輸過 2 個案子(一個沒上市、一個還是在賣)，也有 settled 的。(以前的 settlement 就是 branded 給 generic 一筆錢叫他不要賣，但是現在不能這樣，所以會 negotiate 許多的不同條件)

(三)廠區參觀

1. 共約 450 人左右。
2. 每個月做 2,000 個 batch。
3. 共約 40 個產品，其中 6 個產品佔約 80%之業績。
4. QC 要求極高。
5. 只做 oral drug 且不做液體產品。
6. 有超大液晶螢幕顯示 schedule。
7. Capsule 之成本大於 tablet。

(四)小結

美國之學名藥產業，經過 Hatch-Waxman Act 之推動下蓬勃發展，雖然經過多年來之實行顯現出 Hatch-Waxman Act 之一些問題，但著實快速的發展了學名藥並有效降低藥品費用之支出，也因此學名藥之大量運用亦成為全世界各國發展之方向。但由於藥品開發之高困難度，專利藥廠因此利用各式手段來延長甚至阻止學名藥進入藥廠之時間，也因此學名藥廠均需對於未來之發展做出不同之策略。

專利藥廠除了原本之相關專利訴訟做為阻止學名藥進入市場之方法外，還利用申請訴願(citizen petition)或是利用授權之方式讓 authorized generic 進入市場，這些均是專利藥廠延後學名藥進入市場之方式；雖然現在法院已有判決接受學名藥廠之 Declaratory Judgment 之申請，也就是要求專利藥廠若要針對其標的學名藥提起相關專利訴訟必須於當下進行，否則即放棄其提起訴訟之權利；但學名藥廠要如何大規模之應戰，還是有許多策略面需考量。

而依據訪問 Impax 許總經理之內容，學名藥廠除原有學名藥之製造本業外，也需思考其他發展方向之策略；有些藥廠選擇直接進入開發新藥之研究工作，但 Impax 則建議利用特殊劑型之研發(而非新藥)或是發展門檻較高之學名藥來作為在市場勝出之策略。探討 Impax 目前與其他公司合作之內容，即可理解其利用有

專利之特殊劑型(長效型)做為其最有利之合作發展標的；另外 Impax 也推出自有品牌之藥品來佔據市場，並將能量集中火力於中樞神經疾病之單一市場領域中，利用有限之資金迅速的進行研發，策略性的經營市場；而 Impax 對於挑戰專利的部分則十分的積極，每年提撥千萬美元之法務預算做為挑戰專利或是其他之訴訟之用，且公司內部相關學名藥發展標的之決定並非由業務或是研發單向主導，而是由行銷、研發以及法務共同組成一個專案小組分析討論之後提案呈核，確認之後研發單位才開始進行一連串的研究工作，此亦避免研發費用之浪費。

反觀台灣之學名藥狀況，由於市場並不大且有特殊之全民健康保險制度，另外相關法規之規範極不完善，也因此台灣之學名藥廠必須有自己之營運發展策略；此方面許總經理則亦建議台灣之學名藥廠不應繼續發展一般學名藥，而需要開發 super generic 以迎戰市場；事實上，目前台灣之製藥產業其水準已達國際標準，台灣之學名藥也已有外銷至歐、美、日等製藥先進國家之交易進行中，製藥實力已受證明。故台灣學名藥廠如何跨出，除自己之策略建構之外，主要還需要政府法規以及政策之支持，因此推動學名藥之相關完善法規應是極為重要且急迫之事。