出國報告(出國類別： 其他公務有關活動)

出席 2014 年 6 月經濟合作發展組織(OECD)「競爭委員會」會議報告

服務機關： 公平交易委員會

姓名職稱： 蔡蕙安　委員

杜幸峰　視察

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赴派國家： 法國巴黎

出國期間： 103 年 6 月 14 日至 21 日

報告日期： 103 年 7 月 30 日

目　　錄

附錄:

壹、參與會議之緣起及目的：

經濟合作發展組織(OECD)「競爭委員會」（Competition Committee, CC）及其下轄之第2工作小組(WP2)、第3工作小組(WP3)每年固定在2月、6月及10月於法國巴黎OECD總部召開3次會議。「競爭委員會」各項會議主要討論競爭政策及競爭法之制定及執法方向與技巧，以促進執法活動之國際化及促進各國各項政策及法規之透明化；並制定競爭法執行之最佳實務，促進各國之執法合作並對開發中國家進行能力建置。本年6月例會在6月16日至6月19日舉行。

我國於2002年1月1日正式成為OECD「競爭委員會」一般觀察員（regular observer）後，即固定派員出席該委員會會議。本會參與「競爭委員會」相關會議活動，除可與歐美國家直接進行密切互動、交換意見，強化彼此間交流合作外，亦有助於各國對我國競爭政策/競爭法執行成效的了解以及對我國執法面向的建議，且在「競爭政策」議題上，參與相關會議得使我國從遊戲規則的追隨者成為遊戲規則的制定者，此對提升我國國際地位助益頗鉅。

貳、 OECD「競爭委員會」與會人員

經濟合作發展組織（OECD）是由歐、美、日等34個國家所組成，自1961年9月迄今已成立53週年，會員國包括澳大利亞、奧地利、比利時、加拿大、捷克共和國、丹麥、芬蘭、法國、德國、希臘、匈牙利、冰島、愛爾蘭、義大利、日本、韓國、盧森堡、墨西哥、荷蘭、紐西蘭、挪威、波蘭、葡萄牙、斯洛伐克共和國、西班牙、瑞典、瑞士、土耳其、英國、美國、智 利、斯洛維尼亞、以色列、愛沙尼亞，本次出席「競爭委員會」會議人員，除前開OECD 會員國代表外，尚有歐盟、工商諮詢委員會（BIAC）及「競爭委員會」參與者(participants, 即以前之observers，自2013年5月起改稱為participants)，包括我國、巴西、保加利亞、埃及、立陶宛、俄羅斯、南非、羅馬尼亞、印尼、哥倫比亞、馬爾他、祕魯、埃及等13 國代表。

本次我國出席會議人員為公平交易委員會蔡蕙安委員、綜合規劃處杜幸峰視察及服務業競爭處張心怡視察。

參、「競爭與管制第二工作小組」(WP2)會議

6 月 16 日「競爭與管制第二工作小組」(Working Party No. 2 on Competition and

Regulation, WP2)會議，會議由 WP2 主席 Alberto Heimler 先生主持，本日討論議題包括:

一、討論「競爭法主管機關對其特定行為介入事後評估手冊」(Manual on Ex-Post Evaluation of Specific Competition Agencies' Interventions):

(一) 秘書處表示，競爭法主管機關做事後評估主要是可藉由評估相關市場之變動是否與其決策時預測相同，及是否原本支持決策之分析完整正確，以提升未來決策過程品質。秘書處請會員在 7 月底前提供在決定採取事後評估時，有那些要素應納入考量及如何評估有效救濟措施。

(二) 本議題會員關切之問題:

1、應如何蒐集評估資料?

2、如何把質化分析化為量化分析?如何選擇評估方法?

3、由誰來主導評估工作?是否應由機關內部自行進行評估，或委由外部機構對競爭法機關進行評估?

4、競爭法主管機關是否應公開評估結果?

5、何時進行評估才算準確?主管機關決議後 1 年或應等至 4-5 年，還是更久?

6、如何確定市場變化是因為受競爭法主管機關決議影響，而非市場自己本身或外在變動所導致?

7、手冊內容會不會太冗長?美國代表建議應控制在 50-60 頁之間，以免過於冗長。

(三) 主席請大家在 7 月底前提供意見，俾於下次會議中提出第 1 次手冊內容草案。

二、芬蘭報告該國競爭法中納入「競爭中立」規範:芬蘭競爭及消費者局(Finish Competition and Consumer Authority)代表於會中報告，該國在去年修法通過 FCCA 將有權介入公營事業及民營事業之競爭以確保監督競爭中立。FCCA 將可介入協調因政府政策(如租稅減免或優惠、法定地位優勢)而產生之公營事業商業競爭優勢。如協調未成，FCCA 將可對公營事業課以有條件之處分及義務，以禁止該等扭曲市場競爭之行為。

三、「資助寬頻網路鋪設」圓桌會議(Roundtable on the Financing of the Roll-out of Broadband Networks):

(一)本圓桌會議主要討論 OECD 國家如何資助必要基礎建設以提供寬頻服務接續網際網路，共有 14 國提出報告，討論主要聚焦 2 項主題:政府如何資助及確保寬頻網路之全面舖設，及如何促進基礎建設之競爭。許多國家報告指出，

其中央或地方政府都會補助偏遠地區之寬頻網路建設，但也有些國家僅仰賴民營公司之投資(如瑞典)，而政府補助並非影響民營公司是否在這些偏遠地區投資的主要考量因素。

(二)主要國家報告如下:

1、美國：截至 2013 年 6 月止，鄉鎮有 42.5%及都市有 89.6%之人口數，已能使用最少 50m 之高速寬頻網路服務。但由於網路鋪設之高資本支出及無法獲得全部外部利益，使得私人企業投資意願不足。在美國部分城鎮，必須自行或與其他私人企業合作建設及營運地區型網路。惟目前仍有部分州政府之法規，限制了自治市提供寬頻網路服務的權限，美國國會已提出資助方案，以解決城鎮之網路鋪設問題。

2、日本：截至 2013 年 3 月止，在政府推動下，日本寬頻網路覆蓋率已近 100%，其中光纖網路(FTTH)部分，因鋪設光纖網路成本高昂，政府為促進私人企業對於光纖網路之投資意願，提供低利率貸款、擔保、利息補貼、稅收利益等獎勵措施，並對於偏鄉地區之網路鋪設給予補助。目前日本光纖網路用戶數已超過 ADSL 用戶數。而在智慧型手機普及下，使用行動高速上網之用戶數，亦已超過固網寬頻之用戶數。

3、歐盟：2009 年歐盟訂有「歐盟對於政府補助寬頻網路快速佈建規則之處理原則」(EU Guidelines for the application of State aid rules in relation to the rapid deployment of broadband networks)，以評估寬頻建設補助措施。嗣後因應科技發展，經過專家諮詢及研究，於 2013 年完成新版的修訂。由於私人企業投資光纖網路鋪設之意願不足，歐盟於過去 3 年已補助私人企業鋪設光纖網路之金額達 95 億歐元。歐盟在提供補助前會進行平衡測試(balance test)，衡量補助之正面效果及如競爭扭曲之潛在反面效果，且在沒有其他比政府介入更好方法之原則下才會提供補助。

4、瑞典：瑞典寬頻建設之基本原則，係政府提供良好的市場環境及減少發展障礙，由市場參與者提供通訊及寬頻上網服務，政府僅在偏遠及人口稀少而私人企業無投資意願之處介入。該國對於私人企業寬頻網路建設之補助，係依據「歐盟對於政府補助寬頻網路快速佈建規則之處理原則」辦理。政府補助金額僅占私人企業投資金額一小部分，以儘量避免補助造成的競爭扭曲。

5、英國：在歐盟執委會同意下，英國透過「國家寬頻計畫方案」作為該國補

助新世代寬頻存取網路建設之依據。為使補助造成之競爭扭曲最小化，該計畫方案包含受補助之私人企業有開放其他業者網路存取(網路層)之義務等要求，以促進下游寬頻服務(服務層)之競爭。

6、國際通訊聯盟(International Telecommunication Union, ITU)專家 Ms Phillipa Biggs 指出，預測至 2015 年全世界所有國家都應有寬頻網路發展計畫，40%以上發展中國家的家庭都應可接續網際網路，全世界網際網路使用者滲透率可超過 60%。

7、主席結論指出，寬頻網路建設在各國已是施政之優先項目，但如何資助寬頻舖設各國不大相同。在管制者及廠商間亦存在不對稱資訊，如何提供基礎建設之接續及使用基礎建設之競爭是關切之要點。競爭才能引領至健全之服務提供。

四、「競爭與生產力聯結說明書」:OECD 秘書處競爭組組長 John Davis 報告「競爭與生產聯結說明書」之最終定稿。本說明書係蒐集有關競爭及競爭政策與經濟成長、生產力及就業關係之學術研究。與會代表一致同意本說明書為闡述競爭與整體經濟成長之有效倡議工具，並同意將說明書提交競爭委員會通過後公布，供會員與非會員參考。

五、「競爭評估工具」:秘書處依會員前次會議討論結果，提出工具書第 3 冊「操作手冊」之修正草案，並請會員在下次會議前提出評論意見。

六、「公私夥伴關係」(Public-Private Partnership，PPP)聽證會:

(一)本聽證會討論政府為何選擇 PPP、PPP 的優缺點為何、如何選擇民營單位、何種制度背景有利於 PPP 的有效利用、契約的設計對所提供的服務品質及價格有何程度上之影響、及如何避免 PPP 導致過高投資風險報酬利潤。

(二)OECD 經濟處經濟學家 Sonia Araujo 報告 OECD 國家使用 PPP 概況及其契約特性:

1、2008 年 OECD 經濟政策委員會「總體經濟與架構政策分析」第一工作小組(Working Party No. 1 on Macroeconomic and Structural Policies Analysis)計畫「基礎建設投資:經濟成長與公共政策之關聯」(Infrastructure Investment: Links to Growth and the Role of Public Policies)報告中指出，所稱之基礎建設指能源事業(電力與瓦斯)、水、交通運輸(鐵路、公路、航空運、水路)及電信。

2、運用民營事業參與基礎建設之動機通常為:財務專長、分攤風險、創新方

法、提升成本效能、管理能力以協調不同階層、引進競爭壓力及舒緩預算壓力。

3、PPP 的特徵在於:

(1) 決策架構係結合建設與營運過程，與傳統公共工程採購決策不相同。大多數 OECD 國家係採用「全生命週期」方式(whole-life cycle)計算淨利益，並諮詢獨立機構及進行事後評估。

(2) PPP 須承擔高交易成本，對於小型低價值之計畫不適用。在部分國家，計畫需超出一定門檻金額方得使用 PPP，並可能允許與小型計畫合併採購，招標前須獲得計畫許可及通過環評。

(3) PPP 的高度複雜性會阻礙競爭而產生可能勾結之結果。主管機關通常採國際標或提高透明度來增加競爭。

(4) PPP 在簽訂約上可以增加特別條款，以保證品質。而 PPP 之契約期限在營運管理上期限特長，增加了管制的不確定性，但亦可以此誘因提高投資及基礎建設之品質，惟在契約的延展或更新上一般較有利於原簽約者。

(三)羅馬第二大學(University of Tor Vergata, Rome)教授 Elisabetta Iossa 報告如何改進 PPP 之利用及限制可能之契約扭曲以促進競爭。他指出:

1、PPP 不一定較有效率，且因民營事業需考量風險分攤，建設成本也不一定較便宜。但政府可利用 PPP 舒解財政壓力，有效利用民間資金投入基礎建設。

2、一般 PPP 特許期限都很長，有的超過 50 年甚至到 95 年(如法國)，但重點是如何設計契約以防止競爭被扭曲。

3、某些國家鼓勵民營事業主動提出有益於建設之提案，在提案程序上可能會有不透明化而阻礙競爭，而且主動提案者在招標上有優勢。

4、因缺乏調和性而導致法律不確定性，可能阻礙跨國投標的參與，造成國內企業一家獨大。

5、政府必須注意契約的設計及實務之執行，蒐集並允許他國分享資訊及經驗以達到全面分析效果。

(四)巴黎企業管理學院(IAE de Paris-Sorbonne Graduate Business School)教授 Stephane Saussier 報告法國利用 PPP 之經驗並與特許契約比較。

1、以 2011 年為例，民間融資(Private Financed Initiatives, PFI)在法國資助了大

約 8-9%的公共投資，雖僅為一小部分，但仍屬重要，因為他們資助了一般透過特許契約可能無法達成之公共基礎建設。

2、PFI 的特色通常為:全球性契約、延遲償還、由全體國民支付，透過政府機關直接償還。

3、特許契約也可能有全球性契約，風險也可能會全部或部分轉移給民間事業，某些法國的 PFI 事實上也可以被歸類為特許事業。而某些特許事業可能不用承擔任何風險，主要的魔鬼就藏在契約的細節裏。

(五)義大利羅馬 Luiss Giudo Carli 大學 Dr.Federico Antellini Russo 教授報告義大利利用 PPP 之經驗。

1、在義大利，2013 年的招標案中有 44.2%為建設標案，這些建案中 19.5%為 PPP 標案。在所有 PPP 標案中，低於 1500 萬歐元的計畫佔 97%，而超過 1500 萬歐元的僅有 3%。

2、人平均收入較低的城市似乎較喜歡運用 PPP 計畫，但很少進行精細之評估，亦顯少有監督計畫。大部分的這些 PPP 契約不需太多的專門技術及創新，符合環保或自動展延條款也常於契約中從缺。

3、PPP 計畫的選擇似乎僅依關鍵的平衡條件(即政府赤字增加，PPP 招標的數量也增加)，而完全依「使用者付費」的 PPP 計畫(完全不依賴政府投資)幾乎非常罕見。

4、政府可考量修訂法令規範 PPP 的選擇，以符合歐盟規範，並避免複雜的財政架構。

(六)工商諮詢委員會(BIAC)則從廠商之觀點提出評論，認為一般 PPP 計畫皆屬大型公共工程，應召開國際標以促進競爭，且因該等工程皆屬地方或國家政府所有，應避免政治力之介入，並鼓勵 OECD 持續探討此一議題。

(七)主席結論認為，討論 PPP 最重要的是如何將契約標準化，在競爭研析中最難取得的是資料，PPP 計畫資料的取得應用應十分謹慎，而民營企業在投資時，亦應評估其所該擔負之投資風險。

七、未來工作:下次會議將舉行「競爭政策對生產力及經濟成長之影響」及「政府介入影響評估」公聽會，並將討論 2013-2014 年工作計畫。

肆、「合作與執法第三工作小組」會議:

6 月 18 日舉行「合作與執法第三工作小組」(Working Party No. 3 on Co-operation and

Enforcement, WP3)。會議由 WP3 主席美國司法部反托拉斯署署長 Mr. William Baer 主持，本日討論議題包括:

一、「加強執法合作」聽證會(Hearing on Enhanced Enforcement Cooperation):

(一) 聽證會首先由美國第 7 巡迴法法官 Diane P. Wood 報告「競爭案件中之國際合作－法院之角色」(International Cooperation in Competition Cases－The Role of the Courts)，說明法院在競爭法案件中國際合作之角色。

1、美國市場受到海外廠商聯合行為侵害時，美國法院通常是利用國際禮讓原則來處理。非正式國際合作在國際禮讓原則上有下列原則可供考量:

(1) Charming Betsy 原則:如果有任何其他可能解釋存在，立法行為決不會建立在違反國際法上。

(2) 反域外適用推定原則:除非另有明定，一般立法皆預設僅適用於自己領域。

(3) 屬人管轄權原則:必須存在有最低度接觸法則及公平與實質正義原則。

2、在平行訴訟(多國法院受理相同案件)上，法院必須考量不方便法院原則(Forum non conveniens) 、應禁止重複起訴原則(lis pendens)及禁訴令(Anti-suit injunctions)是否適用於競爭法案件。

3、法院正式合作則可透過調查委託書(letters rogatory)、海牙民商事公約取得所需證據。

4、在對國外判決的執行上，一般而言並無多邊公約或協定可供遵行。美國法院對國外金錢判決之執行是由州法律規範，且有互惠原則之問題。

(二) 以色列海法大學法律學院(Faculty of Law, University of Haifa)Michal Gal 教授報告「判決之自由移動:透過司法互信嚇阻國際卡特爾」(Free Movement of Judgments: Increasing Deterrence of International Cartels Through Jurisdictional Reliance)，提出競爭法主管機關相互承認其對卡特爾案件判決以達成合作之觀點。

1、國際卡特爾對經濟造成嚴重損害，應採「懲罰>利潤」才能有效嚇阻卡特爾行為。但問題是，卡特爾的偵測機率低，如果各國同時進行調查可能造成重複成本，而且大多數國家並不提起刑事訴訟，各國僅依卡特爾對其國內所造成損害予以處分。

2、過去 5 年小型及發展中國家幾乎沒有對卡特爾案件之調查處分，這是因

為這些國家缺乏人力及財力處理這類跨國卡特爾案件，而且這些跨國公司通常都聘有優秀律師團，更具有政治影響力，因此在這些國家也無法獲得因卡特爾造成的損害賠償。

3、如果採取跨國判決相互承認，可減少人力及資金的重複運用，也可降低部分的政治影響力。重點是，必須確保所有決議是符合國外法律，且皆符合正當程序，事證明確。

4、此一方法的最大缺點是傷及國家主權，且在部分國家可能會有執法過當或執法不力之虞，並降低了寬恕政策的成效。

(三) 德國伊爾默瑙工業大學經濟學院(Institute of Economics, Ilmenau University of Techno1ogy)O1iver Budzinski 教授報告「朝向合理化多重競爭政策執法程序:主導管轄權概念之角色」(Towards Rationalizing Multiple Competition Policy Enforcement Procedure:The Role of Lead Jurisdiction Concepts)，提出「以單一管轄(即其主管機關)主導之共同程序取代未協調的多重程序」(Uncoordinated multiple procedures are replaced by common procedure led by a single competent jurisdiction(its authorities respectively)之概念，以強化國際合作。

1、所謂主導管轄模式(lead jurisdiction model)即未經過協調之多個國家程序由一個單一主管領域(主管機關)之共同程序取代。其因主導國權限不同區分為:

(1) 自願主導國:自願主導國係擔任協調者之角色，彙整並分配證據，依據相互禮讓原則提出非強制決議建議。案關國家仍得各自依法查處案件。

(2) 委任主導國:主導國處理案件所有事務(單一窗口)，其調查權力由所有受影響國家協助賦予，而主導國之決定對所有受影響國家具強制性。

2、多層次監協調機制:

(1) 由一中介組織(國際或全球性)負責監督主導國能否公允處理案件，並解決跨國案件所涉國家之衝突。

(2) 至於實際件查處則由現存競爭體制解決，包括國家/區域(如歐盟)/次級政府(如美國各州)。

3、惟上開觀念觸及國家主權概念，會員皆表示尚有待更多討論。

4、 Cleary Gottlieb Steen & Hami1ton 法律事務所 John Temple Lang 律師則認為法院之合作僅仰賴判決並非可靠，他認為國際合作應以「單一窗口」

(one-stop-shop)或兩機關間更緊密合作來達成，並應避免衝突事項，如結合審核時程、不同之補救措施等。

5、 歐盟報告其會員國競爭法主管機關如何合作協調處理業務檢查(inspections)及突襲搜索(dawnraids)。荷蘭報告其在「歐洲競爭網絡內」(ECN)合作共同採取突襲搜索行動之經驗。

6、 加拿大報告該國在結合案與美國及其他 OECD 會員交換資料及討論補救措施之經驗，澳洲則報告 ACCC 與紐西蘭商業委員會在澳紐加強合作協定下，兩國競爭法機關自 2010 年開始相互指派共同委員(associate members)及共同委員在結合案之成功合作經驗。

7、 會員所提意見皆認為合作對執法非常重要，但必須考量下列問題:(i)各國在跨境處分之程度及處分書內容是否可能一致；(ii)合作時語言之限制(英語是否為必要之共通語言，承辦人使用共通語言之能力限制)；(iii)溝通合作時層級之考量。

8、 BIAC 建議卡特爾案中寬恕政策之申請應採單一窗口制，以提高業者提出申請之誘因。

二、修正 1995 年國際合作建議書:秘書處提出修正後之「國際合作建議書」草案供會員討論。工商諮詢委員會(BIAC)認為建議書中有關機密資訊之交換，其中第 7 條第 10 項建議會員可不須經過當事人同意，透過非正式管道交換機密資訊乙節，將造成主管機關與業界「雙輸」(lose-lose)之局面，且業界會有「寒蟬效應」(chilling effect)而不再提供競爭法主管機關機密資訊，請會員考慮修正此點。惟會員討論後認為競爭法主管機關皆非常重視機密資訊之保護與應用，應無 BIAC 所提之問題，爰一致同意將本修正草案提交競爭委員會討論通過後，再提交總理事會討論。

三、討論「寬恕政策有效性與採購機關及其他執法者所課予制裁間之關係」(Relationship between the Effectiveness of Leniency Programmes and Sanctions Imposed by Procurement Authorities and Other Enforcement):各國代表提出其與政府採購部門調查合作協調經驗，並建議 OECD 會員協助採購部門瞭解寬恕政策之施行及其成效。

四、討論「已完成與未申報結合案件之補救措施經驗」:本議題延續 2 月圓桌會議「已完成與未申報結合案件之調查」題目，就有關補救措施提出討論。美國代表報告美國司法部反托拉斯署最近在對 Bazaarvoice 結合訴訟時，其所面對事業已完成

其資產整合，如何研擬可行之補救措施，以回復競爭問題。英國及智利代表亦提出結合自願申報制度可能面臨相同問題及其處理之經驗。

五、未來討論主題:下次會議將舉行「資格保留在卡特爾寬恕政策之運用」圓桌會議(Roundtable on the Use of Markers for Cartel Leniency Programmes)，並繼續依本次國際合作聽證會結果，討論國際合作長期策略。

伍、「競爭委員會」會議:

6 月 19 日至 6 月 20 日舉行競爭委員會(Competition Commission, CC)會議，由主席 Dr. Frédéric Jenny 主持，討論事項如下

一、6 月 18 日:

(一) 各工作分組主席及國際組織協調人報告:

1、WP2 主席 Alberto Heimler 報告 6 月 16 日會議情形及結論

2、WP3 主席 Wi11iam Baer 報告 6 月 17 日會議情形及結論。

3、UNCTAD 協調人 Francois Souty 博士報告:UNCTAD 將於 7 月 7 日至 11 日在日內瓦舉行競爭法專家會議。

4、ICN 協調人加拿大競爭局局長 John Pecman 報告本年 4 月 ICN 年會在摩洛哥舉行情形，及本年將次第舉辦之各項研討會:(1)本年 10 月 1-3 日在我國舉辦卡特爾研討會。(2)11 月 6-7 日將在模里西斯舉辦倡議研討會，(3)12 月 1-2 日在印度新德里舉辦結合研討會。

(二) 通過「競爭與生產力聯結說明書」:會員同意通過秘書處所擬之「競爭與生產力聯結說明書」，做為會員宣導倡議之輔助資料。

(三) 修正通過「1995 年國際合作建議書」:BIAC 於會中繼續提出對使用非正式管道交換機密資訊之修正意見，惟與會各國代表皆認為競爭法執法機關對機密資訊之保護與運用十分謹慎，故不應修正。秘書處建議該合作建議書最後一段每 3 年向總理事會提出報告乙節，修正為每 5 年向總理事會提出報告。會員一致同意該修正案並同意提報總理事會討論。

(四) 長期策略主題:CC 繼續討論 2015-2016 年 2 年間之策略主題。除同意延續 2013-2014 之「國際合作」主題繼續討論外，會員將在「智慧財產權」、「競爭中立」、「垂直限制」及「評估」等主題中，擇一做為未來 2 年之討論主題。

1、就智慧財產權，秘書處認為，並非許多競爭法主管機關有智慧財產權之相關問題，CC 將於下次會議討論競爭法主管機關與智慧財產權主管機關間之關

係，以決定是否可提供相關討論文件。

2、部分會員認為「競爭中立」主題具有相當之政治敏感性，秘書處應詳細規劃執法項目，並與其他委員會討論此一主題。主席認為應先釐清有何種「政治敏感性」及來自何處，此一主題在貿易談判中相當重要。CC 將繼續與其他委員會協調此一主題之討論。

(五) 會議時程變更:主席宣布，CC 原訂本年 10 月 27-31 日會議將移至 12 月 15-18 日舉行。明年起會議將由一年 3 次變更為一年 2 次，每次會議 5 日，且原每年 2 月舉行之「全球競爭論壇」將因配合每年 4 月 ICN 舉辦年會之關係，移至下半年會議舉行。明年會議暫訂為 6 月及 10 月，2016 年起每年 6 月及 11 月舉行會議。

(六) 「學名藥競爭」圓桌會議:

1、本圓桌會議議題主要討論自 2009 年以後，學名藥產業之重要競爭議題及競爭法主管機關如何執法與促進學名藥在藥品產業之競爭。本圓桌會議共有 17 個會員提出報告，委員會並邀請哥倫比亞大學 Scott Hemphill 教授及 Cleary Gottlieb 法律事務所合夥人 Romano Subiotto 提出報告。

2、主席依「學名藥之發展」、「阻礙競爭之單方行為」及「限制競爭協議」三大議題依序討論。

3、日本報告該國學名藥之發展。

(1) 日本在 2012 年處方藥規模約 95 兆 6010 億日圓，學名藥占其中之 9 兆 8960 億，約為 10.3%，比重上已自 2006 年的 4.5%快速提升。在製造商部分，日本境內約有 200 家學名廠商，2012 年之產值約占市場 67.5%，除 Teva Pharma Japan Inc. 1 家以外，其餘皆與原廠藥無關聯。

(2) 依「日本國民健康保險藥品價格標準」，學名藥之價格大都較原廠藥便宜。學名藥在日本之上市與銷售皆須經過厚生勞動省(Ministry of Health, Labor and Welfare, MHLW)核准，如果與原廠藥有任何專利問題，須由學名藥廠商與專利藥商先行諮詢，如有爭議則由 MHLW 進行協調。為鼓勵提高使用學名藥，MHLW 於 2007 年公布「促進學名藥的安全使用行動計畫」(Action Programme for Promoting the Safe Use of Generic Drugs)，並設定在 2012 年市場規模達 30%以上之目標。

4、法國:法國學名藥較不受病人及醫藥從業人員之信任，故在保險可核銷給付之學名藥僅占市場規模不到 1/4，而此一項目在德國、英國、美國皆超過 2/3

以上。法國競爭委員會在 2013 年 2 月 25 日決定對人類服用之處方藥行銷依職權主動進行市場調查，並在同年 7 月至 9 月進行大眾意見諮詢，該調查結果於 2013 年 12 月 19 日公布。報告主要聚焦在與學名藥有關之競爭議題:

(1) 競爭委員會在該報告中強調藥品產業中創新發明之重要性，因為可以強化廠商間之競爭並提高產業就業率。報告中亦強調學名藥可以促進原廠藥商繼續研發，亦可使國家健保基金會節約支出，以支付更高額的創新藥品。

(2) 競爭委員會並指出，學名藥產業可能面臨之競爭管制問題包括:學名藥之給付價格偏低、國家藥品安全局所核准之學名藥及生物相似藥清單數量太少、專利權的保護及對學名藥成效的詆毀。

5、Scott Hemphill 教授報告「學名藥競爭的不當延遲」(Unjustified Delay in Generic Drug Competition):

(1) 學名藥的提早進入市場可迫使原廠藥降低價格，兩者間之價格競爭有利於消費者。

(2) 1984 年美國 Hatch-Waxman 法建立學名藥進入市場的法律架構，學名藥廠商須等專利到期後方能生產該項藥品，而原廠藥商亦因此加強保護其專利權。2000 年至 2002 年間之美國新藥專利幾乎為 1985 至 1987 年間藥品的 2 倍，複項專利及專利期間重疊使藥品之專利保護更加延長。反托拉斯主管機關對此無從置喙，但這樣的專利延長保護不一定有利於消費者。美國最高法院已駁回專利權可凌駕反托拉斯法或其他政策之看法，專利及藥品管制機關必須就低價學名藥之可取得性及專利保護與鼓勵創新發明上取得平衡。

(3) 另一延遲學名藥競爭之行為則為勾結，原廠藥以延遲給付(delay payment)方式與學名藥取得延後進入市場協議，以獲取更長期間的市場獨占利潤。2013 年 6 月美國最高法院認定延遲給付可能違反反托拉斯法後，在美國至少已有 18 件延遲給付之反托拉斯訴訟案件正在進行中。另一限制競爭行為則為學名藥廠商間互相勾結，不相互挑戰其進入市場競爭之資格，以延長藥品之高售價期間，獲取較高之利潤。

(4) 學名藥亦可能受原廠藥單方行為阻礙而無法進入市場，如原廠藥商將現有藥品以新型態，包括改變藥品形狀(膠囊改為藥錠)、延長藥方釋出期限、及宣稱加入更強效成分等，以吸引病人及醫生繼續使用該藥品。此種

產品跳躍(product hopping)或產品轉換(product transfer)之技倆可能導致學名藥之滯銷而使消費者給付更高額之原廠藥費用。

6、Cleary Gottlieb 法律事務所律師 Romano Subiotto 以「不完備的歐盟專利執法體制對逆向給付和解評估的意含」(The Implications of the Imperfect European Patent Enforcement System on the Assessment of Reverse Payment Settlements)提出報告:

(1) 「逆向給付和解」(reverse payment settlement)指原廠藥與學名藥生產者間專利糾紛和解預期由原廠藥廠商移轉某一金額至學名藥商，亦稱為延遲給付。歐盟對此之評估係基於兩項標準:和解案是否限制學名藥進入市場?和解案是否預見由原廠藥廠商移轉某一金額至學名藥廠商。

(2) 歐盟的專利執法體制有 3 項主要不完備因素，導致原廠藥廠商有強烈的誘因逆向給付給學名廠商: (i)事前執法能力有限，無法有效預防侵權產品的銷售；(ii)即使原廠藥廠商贏得訴訟，亦僅能獲得部分賠償；(iii)歐盟國缺乏一致的專利法制，無法一一對散播於歐盟境內的侵權行為進行執法。

(3) 歐盟對專利和解的競爭評估必須考量專利執法體制的運作。逆向給付可能可以解釋是因專利執法體制之不完備，以及學名藥廠商即使產品可能侵權也要進入市場的抵銷誘因。逆向給付的存在並沒有一般的證據能力可以顯示原廠藥廠商專利權的強弱，亦無法顯示限制競爭是否存在之預設立場。

(4) 逆向給付的金額大小並不能做為專利和解的主要法律訴訟標準，亦無法顯示是限制競爭或有利競爭。只要和解中的限制條件是在有效的專利排他範圍內，和解可能可以達到專利所有權者可能在執行專利法體制中所達到的相同效果而不違反競爭法。

7、主席在「阻礙競爭之單方行為」討論中，請本會代表就報告中所提案例提出說明。本會所提案例為健亞生物科技公司向智慧財產權提起民事訴訟，指稱日商武田藥品股份有限公司明知其「皮利酮」該項藥品專利，卻向台中地方法院誣稱擁有該項專利，並以健亞公司生產之藥品侵害其專利權，聲請核發假處分並獲准執行，導致該公司之藥品無法上市販售，該公司之行為涉有違反公平交易法而致其營業受損害。案經智慧財產權法院審理後，二審法庭認定武田公司之行為係故意利用法律所規定之制度遂行其防堵健亞公司競爭

產品進入市場之手段，屬權利之濫用，為足以影響交易秩序之顯失公平行為，違反公平交易法第 24 條規定，而依據同法第 31 條及第 32 條規定，武田公司須依公平交易法及民事訴訟法賠償健亞公司新臺幣 5,000 萬元，並自 2009 年 4 月 22 日起至清償日止按週年率百分之五計算之利息。武田公司雖上訴至最高法院，惟其上訴於 2012 年 2 月 23 日為最高法院駁回而確定。

二、 6 月 19 日

(一) 上午舉行「全球關係」(Global Relations)閉門會議，討論羅馬尼亞申請加入 OECD 案。

(二) 反托拉斯遵法計畫:

1、國際商業總會(International Chamber of Commerce, ICC)報告該會所研訂之 ICC 反托拉斯遵法計畫工具書(The ICC Antitrust Compliance Toolkit)。

2、該工具書係 ICC 在 2010 年為中小企業及較大公司所研訂，該會也建議競爭法主管機關與企業就遵法計畫進行對話。

3、ICC 指出，企業遵法計畫應該是「量身訂製」(Taylor-made)，而非一套適用全數事業(one size fits all)。遵法計畫之執行必須依循「5C」:Commitment(承諾)，Culture(文化)，Compliance Knowledge and Organization(遵法知識及組織)，Controls(管理)，Constant monitoring and improvement(持續監督及改進)。

(三) 航空業競爭圓桌會議:

1、本圓桌會議計有 33 篇報告，主席將各國報告分為「航空業在解除管制環境中運作及競爭」、「影響競爭之因素」、「航空業之競爭議題及反托拉斯執法」及「未來挑戰及演進」等四大議題進行討論，並邀請專家提出報告。

2、主要國家及專家報告如下:

(1) 日本：因日本公平交易委員會對於 2001 年日本航空和佳速航空結合案對國內航空市場之限制競爭疑慮，參與結合事業作出釋出部分時間帶(slots)予日本國土交通省、票價調降 10%及 3 年內票價不調漲等承諾。日本國土交通省因此重新就時間帶進行分配規劃，並將新增之時間帶分配予市場新進業者，俾使市場新進業者得以與市場領導者競爭。在前開補救措施之施行下，雖使日本國內航空市場不至於因該結合案減損競爭，惟參與結合事業卻仍無法因該結合案改善財務狀況而破產，直至 2010 年才在內部重整及政府協助下重生。

(2) 韓國：該國航空法對於航空業者申請執照、營運許可及航線等相關規定，

實際上係對新進業者參進市場造成限制。故 2010 年韓國公平交易委員會向直屬總統之「國家競爭委員會」提報管制改善計畫。改善計畫內容主要包括：(一)讓廉價航空業者得以參與出席時間帶規劃委員會。(二)除原有之仁川機場外，亦讓金浦機場及濟州島機場列入策略時間帶政策範圍內。(三)放寬對小型航空業者取得營運許可及保險等相關規定。

(3) 紐西蘭：紐西蘭競爭委員會認為常客計畫(FFP)雖可能造成其他航空業者(尤其班次較少之新進業者)因無法提供旅客相應之 FFP，而對於目標客群存有進入障礙。惟 FFP 亦屬一種競爭手段，不見得不具正面之競爭效果。至於高等法院則認為 FFP 影響的僅是特定層級之潛在客群，縱可能造成新進業者藉由 FFP 與既有業者分享客群之限制，但 FFP 並不至於造成市場進入障礙。

(4) 澳洲：澳洲競爭及消費者委員會(ACCC)對於市場界定，係採取目的性方法(purposive approach)，而不單獨就系爭產品(服務)進行相關市場界定。就航空業來說，將避免因過於窄化市場界定，而導致在進行競爭效果評估時，忽略其具有之網路效果。因每條航線有不同之市場情況，故應就特定航線進行個別分析。

(5) 美國：針對全美航空及美國航空之結合，係採行參與結合事業放棄特定機場部分時間帶予其他航空業者(如廉價航空)等補救措施。前開補救措施雖無法完全補救因該結合對競爭之損害，惟其主要目的是有效地降低廉價航空進入及擴張市場之障礙，及改善市場結構，進而得使消費者獲得利益。

(6) 歐盟：航空業者之聯盟，只有在導致限制或減損競爭之情況下，亦即倘航空業者間就費率、載客量及航班安排等影響競爭之要素進行合作時，尤其有利潤分配之情形下，歐盟才會展開反托拉斯調查，並進行效率評估，包括是否因航班分配節省時間、是否具有密度經濟、候機室互相使用及減少雙重邊際化之利益等項目。

(7) 秘書處將本會所提交報告排入「航空業之競爭議題及反托拉斯執法」之「水平協議」部分，惟由於時間關係，主席並未邀請本會說明報告內容。

(四) 未來討論題目:下次會議 CC 將討論「制度之設計:最近之經驗及所習得之教訓」(Institutional Design: Recent Experiences and Lessons Learnt)及與智慧財產權有關之「標準設定」(Standard Setting)。

陸、 心得與建議

一、WP2 本次討論「資助寬頻網路舖設」議題，本會雖未提出報告，但討論內容與我國未來寬頻網路之發展及競爭相關,本議題會議資料建議函送 NCC 及交通部參考。

二、競爭委員會本次討論「學名藥競爭」議題，對學名藥市場發展、原廠藥與學名藥競爭，及各項可能違反競爭法行為之皆有相當詳細之討論，有助於本會對藥品市場競爭行為及調查方向之瞭解，建議提供衛生福利部做為推動學名藥發展之參考。

三、另競爭委員會討論之「航空業競爭」議題討論內容包括廉價航空加入市場後航空業之發展、各項關鍵設施之分配、航空公司結合之審查考量要素、垂危事業之處置等，內容與管制機關之政策有關，建議函送交通部參考。

四、本次會議資料相當豐富，各議題討論內容及各國報告值得本會參考。為利同仁瞭解國外實務之做法,相關會議文獻資 料將建置於本會BBS 網站供同仁參閱利用。

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Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

02-Jun-2014

English - Or. English

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE

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Working Party No. 2 on Competition and Regulation

DRAFT AGENDA OF THE 57th MEETING OF WORKING PARTY No. 2

16 June 2014

-- Starting at 10.00 a.m. --

To be held on 16 June 2014 in Room CC 1 of the Conference Centre, 2 rue André Pascal, 75116 Paris, France.

Please contact Ms. Cristiana Vitale if you have any questions regarding this document [E-mail: cristiana.vitale@oecd.org].

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English - Or. English

DRAFT AGENDA OF THE 57TH MEETING OF WORKING PARTY NO. 2

16 June 2014, from 10.00 – 18.00
OECD Conference Centre, Room CC 1
2, rue André-Pascal, 75116

I. ADOPTION OF THE DRAFT AGENDA

DAF/COMP/WP2/A(2014)2/REV3

II. ADOPTION OF DRAFT SUMMARY RECORD FROM LAST MEETING

-- Draft Summary Record from the last meeting — DAF/COMP/WP2/M(2014)1/REV1

-- List of Participants to the meeting of February 2014 — DAF/COMP/WP2/M(2014)1/ANN1

III. MANUAL ON EX-POST EVALUATION OF SPECIFIC COMPETITION AGENCIES' INTERVENTIONS

For discussion:

-- Note by the Secretariat — DAF/COMP/WP2(2014)12

IV. ROUNDTABLE ON THE FINANCING OF THE ROLL-OUT OF BROADBAND NETWORKS

For discussion:

-- Country contributions

Belgium	DAF/COMP/WP2/WD(2014)15
Denmark	DAF/COMP/WP2/WD(2014)13
France	DAF/COMP/WP2/WD(2014)12
Japan	DAF/COMP/WP2/WD(2014)11
Netherlands	DAF/COMP/WP2/WD(2014)7
Sweden	DAF/COMP/WP2/WD(2014)3
Switzerland	DAF/COMP/WP2/WD(2014)17
Turkey	DAF/COMP/WP2/WD(2014)14
United Kingdom	DAF/COMP/WP2/WD(2014)2
United States	DAF/COMP/WP2/WD(2014)9
European Union	DAF/COMP/WP2/WD(2014)10

and
Colombia DAF/COMP/WP2/WD(2014)8
Lithuania DAF/COMP/WP2/WD(2014)6
BIAC DAF/COMP/WP2/WD(2014)4

For reference:

-- Next Generation Access Networks and Market Structure DSTI/ICCP/CISP(2010)5/FINAL

-- The State of Broadband 2013: Universalizing Broadband
A report by the Broadband Commission (Sept. 2013) is available in the following link:
http://www.broadbandcommission.org/Documents/bb-annualreport2013.pdf

V. UPDATES BY FINLAND AND UNCTAD

-- Note by UNCTAD DAF/COMP/WP2/WD(2014)18

VI. FACTSHEET ON THE LINKS BETWEEN COMPETITION AND PRODUCTIVITY

For discussion:

-- Note by the Secretariat DAF/COMP/WP2(2014)13

VII. COMPETITION ASSESSMENT TOOLKIT

For discussion:

-- Note by the Secretariat DAF/COMP/WP2(2014)2/REV1

VIII. HEARING ON PUBLIC-PRIVATE PARTNERSHIPS

For reference:

-- Paper by Elisabetta Iossa DAF/COMP/WP2/WD(2014)1

-- Paper by Antellini Russo, F. and Zampino, R. (2012). DAF/COMP/WP2/WD(2014)16
"Infrastructures, Public Accounts and Public-Private Partnerships:
Evidence from the Italian Local Administrations". *Review of Economics and Institutions*, 3(1), Article 4. doi: 10.5202/rei.v3il.61.

-- Paper by Araújo, S. and D. Sutherland (2010),
"Public-Private Partnerships and Investment in Infrastructure",
OECD Economics Department Working Papers, No. 803,
OECD Publishing. is available in the following link:

http://dx.doi.org/10.1787/5km7jf6q8f0t-en

-- Paper by Burger, Philippe and Ian Hawkesworth (2011),

"How To Attain Value for Money: Comparing PPP and
Traditional Infrastructure Public Procurement",
OECD Journal on Budgeting, Vol. 11/1. is available in the following link:
http://dx.doi.org/10.1787/budget-11-5kg9zc0pvq6j

-- OECD Recommendation on Public Governance of PPPs is available in the following link:
http://www.oecd.org/gov/budgeting/PPP-Recommendation.pdf

IX. FUTURE TOPICS AND OTHER BUSINESS

ANNOTATIONS

PROPOSED TIMETABLE

10h00 – 10h20	**Items I - II**
10h20 – 10h50	**Item III** (Manual on Ex-post Assessment)
10h50 – 13h00	**Item IV** (Financing of Broadband Networks)
13h00 – 15h00	**LUNCH**
15h00 – 15h20	**Item V** (Updates from UNCTAD and Finland)
15h20 – 15h40	**Item VI** (Links between Competition and Productivity)
15h40 – 16h00	**Item VII** (Competition Assessment Toolkit)
16h00 – 17h50	**Item VIII** (Public-Private Partnerships)
17h50 – 18h00	**Item IX** (Future Topics and Other Business)

Item III

In February 2014, WP2 examined the outline of a *Manual on the ex-post assessment of competition authorities' specific interventions*. This Manual will provide guidance on what authorities need to consider if they decide to perform assessments and will offer a wealth of detailed examples and references (both academic papers and studies conducted by CAs). Its aim is to be a useful reference document for economists in competition agencies that are tasked with performing ex-post assessments. A new version of the outline of the Manual, which provides more details on its content, will be discussed. This document will be circulated in advance of the meeting.

Item IV

Many countries have set ambitious objectives of national high-speed broadband coverage. Investments by private telecom companies may not be enough to reach these objectives, in particular in less populated rural areas, since the upfront investments required to deploy the necessary infrastructure are very high and the returns uncertain. Hence, national and local governments have been exploring alternative solutions to fund this infrastructure, ranging from allowing private joint ventures between competing telecom companies, to providing public funding and participating in public-private partnerships.

This two-hour roundtable will be based on country contributions and will examine alternative ways in which governments are ensuring the deployment of the infrastructure necessary to ensure high speed broadband access across their territory. In particular the discussion will focus on: when and why governments are getting involved in the development of the infrastructure rather than rely on market forces, what forms this involvement is taking, and if and how the real need for public intervention has been assessed. The discussion will benefit from an intervention by Ms Phillippa Biggs (International Telecommunication Union, Geneva).

Please refer to the letter from Chairman Heimler for more details on this roundtable. A paper from the Science Technology and Industry Directorate on *Next Generation Access Networks and Market Structure* will be circulated in advance for reference, together with a report by the Broadband Commission on the *State of Broadband Deployment around the World*.

Item V

Finland will present the new provisions on competitive neutrality that have been introduced in the Finnish Competition Act.

UNCTAD will outline the results of a recent review of competition law, policy and institutions in the Economic Community of West African States (ECOWAS), which has led to an innovative reform of the competition regime in the member countries. The presentation will also examine an ongoing project directed at developing a model of regional application of competition law in Central America.

Item VI

The Secretariat will present the final draft of a factsheet that outlines recent evidence on the links between competition and productivity, as well as other macro-variables, such as employment and growth.

This new draft includes all the comments and suggestions received after a first draft was discussed in June 2013. The aim of this document is to provide competition agencies with an additional tool to use in advocating their role. The factsheet will be circulated in advance of the meeting.

Item VII

Assessing the competitive impact of different types of government policies can yield substantial benefits, whether for businesses -- by increasing the purchasing, production, marketing and sales options - or for consumers -- by enhancing choice, lowering prices, and/or raising quality. The *Competition Assessment Toolkit* provides methods and techniques for determining the likely impact on competition of various types of policies, such as permits, price regulations, advertising restrictions and many others.

The Working Party will discuss a revised version of the Operational Manual (Volume 3) of the Competition Assessment Toolkit, which takes into account all the comments received since the last meeting. The purpose of the volume is to provide an accessible explanation, from a very practical perspective, of how to review regulations for their competitive effects.

The revised draft of the Operational Manual will be circulated in advance.

Item VIII

A public-private partnership (PPP) involves a contract between a public authority (at national or local level) and a private party for the provision of a public service, or the development of an infrastructure, where the private party assumes substantial financial, technical and operational risk in the project. Hence, PPPs are very different from traditional public-private procurement contracts because they involve not just the provision of an infrastructure, but also its operation, and they lead to some form of sharing of the demand risk between the public procurer and the private provider.

Usually PPPs are undertaken to exploit synergies between the various stages of the provision process, to provide incentives to the private partners to internalize operational and maintenance costs in its investment decisions, and to benefit from private partners' managerial capabilities, and technical and sectoral know-how. PPPs can also help to better assess the risk of a project because private parties tend to get involved when there is reasonable certainty of a financial reward.

In the last twenty years a number of developed and developing countries around the world have used PPPs in a variety of sectors, ranging from transport and utility infrastructures, to schools, hospitals and prisons.

This Hearing will discuss why governments choose PPPs, what are the major benefits and the major drawbacks of PPPs, how the private parties are selected, what institutional context favours an effective use of PPPs, to what extent the design of the contract has an impact on the quality and price of the services provided; and how to avoid that the PPPs may lead rents (i.e. profits above those that reward the investments undertaken and the risk assumed) for the private parties.

The discussion will benefit from the participation of Prof. Elisabetta Iossa (University of Tor Vergata, Rome and CEPR, London), Prof. Stéphane Saussier (IAE de Paris – Sorbonne Graduate Business School), Dr. Federico Antellini Russo (Economist, Cassa Despositi e Prestiti – Fellow at CASMEF, Luiss Giudo Carli University, Rome) and Dr. Sónia Araújo (Economist, OECD Economics Department). A paper from Prof. Iossa, a Working Paper from the OECD Economics Department, and a paper from the OECD Public Governance and Territorial Development will also be circulated for reference.

Item IX

It was agreed in February that the October 2014 WP2 meeting would be devoted to a Roundtable on the use of tenders for creating competition for the market in those instances where there cannot be competition in the market, with the aim to determine how successful these really are, and if and how their design and implementation could be improved. The meeting will also include the presentation by the Secretariat of a first draft of the *Manual on the ex-post assessment of competition authorities' specific interventions*. In February 2015 the plan is to have a Roundtable on liner-shipping, as well as a discussion of a more advanced draft of the *Manual on the ex-post assessment of competition authorities' specific interventions*. The Working Party will discuss and decide topics for the WP2 June 2015 meeting.

The next meeting of Working Party No. 2 is scheduled for 27 October 2014.

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

07-May-2014

English - Or. English

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE

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Working Party No. 3 on Co-operation and Enforcement

DRAFT AGENDA OF THE 119TH MEETING OF THE WORKING PARTY No. 3

17 June 2014

To be held on 17 June 2014 from 9:30 to 16:45 at the OECD Conference Centre, in room CC 1, 2 rue André Pascal, 75116 Paris.

Please contact Mr. Antonio Capobianco if you have any questions regarding this document [phone number: +33 1 45 24 98 08 -- E-mail address: antonio.capobianco@oecd.org].

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DRAFT AGENDA OF THE 119TH MEETING OF WORKING PARTY NO. 3

17 June 2014, beginning at 9.30 a.m.

OECD Conference Centre, Room CC 1

2 rue André-Pascal, 75116 Paris

I.	**ADOPTION OF THE DRAFT AGENDA**	DAF/COMP/WP3/A(2014)2
II.	**ADOPTION OF THE SUMMARY RECORD OF THE LAST MEETING**	
	-- Summary record from the last meeting of 25 February 2014	DAF/COMP/WP3/M(2014)1
	Approved by written procedure:	
	-- Summary of Discussion of the Roundtable on Remedies in Cross-Border Merger Cases (October 2013)	DAF/COMP/WP3/M(2013)3/ANN2
	For information:	
	-- List of participants for the meeting of 25 February 2014	DAF/COMP/WP3/M(2014)1/ANN1
III.	**HEARING ON ENHANCED ENFORCEMENT COOPERATION**	
	For discussion:	
	-- Note by the Secretariat	DAF/COMP/WP3(2014)3
	-- Paper by Prof. Michal S. Gal	DAF/COMP/WP3(2014)4
	-- Paper by Judge Diane P. Wood	DAF/COMP/WP3(2014)5
	-- Paper by Prof. Olivier Budzinski	DAF/COMP/WP3(2014)6
	-- Paper by Mr. John Temple Lang	DAF/COMP/WP3(2014)7

IV. REVISION OF THE 1995 RECOMMENDATION ON INTERNATIONAL CO-OPERATION

-- Note by the Secretariat DAF/COMP/WP3(2014)8

V. DISCUSSION ON THE RELATIONSHIP BETWEEN THE EFFECTIVENESS OF LENIENCY PROGRAMMES AND SANCTIONS IMPOSED BY PROCUREMENT AUTHORITIES AND OTHER ENFORCERS

VI. EXPERIENCES WITH REMEDIES IN CONSUMMATED AND NON-NOTIFIABLE MERGERS

VII. OTHER BUSINESS AND FUTURE TOPICS

ANNOTATIONS TO THE DRAFT AGENDA

Proposed Timetable

9:30 – 9:35	**Items I.** and **II.**
9:35 – 12:30	**Item III.** Hearing on Enhanced Enforcement Cooperation
12:30 – 14:00	*Lunch break*
14:00 – 15:00	**Item IV.** Revision of the 1995 Recommendation on International Co-operation
15.00 – 15:45	**Item V.** Discussion on the Relationship between the Effectiveness of Leniency Programmes and Sanctions Imposed by Procurement Authorities and other Enforcers
15:45 – 16:30	**Item VI.** Experiences with remedies in consummated and non-notifiable mergers
16:30 – 16:45	**Item VII.** Other business and future topics

Item III. (from 9.30 to 12.30). Under this agenda item, WP3 will host a hearing on "*Enhanced Enforcement Cooperation*". The hearing will help us consider possible new and different forms of co-operation among our agencies. The Secretariat has invited four speakers who will share their insights on possible new forms of co-operation and participate in the discussion:

- Prof. Michal S. Gal (Faculty of Law, University of Haifa, Israel) will present her research on recognition of foreign decisions, and the criteria for such systems to operate in cartel cases;

- Judge Diane P. Wood (U.S. Court of Appeals for the Seventh Circuit, United States) will review the legally approved ways in which courts in different jurisdictions are permitted to assist one another, and how those might help the international cooperation effort;

- Prof. Oliver Budzinski (Institute of Economics, Ilmenau University of Technology, Germany) will present his research on "lead agency" models and discuss how these models could work in practice in the competition enforcement area;

- Mr. John Temple Lang (Cleary Gottlieb Steen & Hamilton LLP, Brussels, Belgium) will reflect on possible models based on the "one-stop-shop" principle, and discuss advantages and challenges of such approaches.

A short Secretariat issues paper will assist delegates in preparation of this discussion. It will put into context this discussion and recapitulate in a non-exhaustive way the issues to be discussed.

Item IV. (from 14.00 to 15.00). Under this agenda item, WP3 delegates will discuss progress on the revision of the 1995 OECD Council Recommendation concerning Co-operation between Member Countries on Anticompetitive Practices affecting International Trade. A draft will be circulated to WP3 delegates in advance of the meeting. Once final, the draft will be transmitted to the Competition Committee. Following approval by the Committee, the Revised 1995 Recommendation will be submitted to the Council in autumn 2014 for adoption.

Item V. (from 15.00 to 15.45). Under this agenda item, WP3 will discuss the "*Relationship between the effectiveness of leniency programmes and sanctions imposed by procurement authorities and other enforcers*". WP3 will hear from those who have raised the issue concerning their experiences with procurement agencies and will discuss measures taken to ensure co-ordination of penalties to protect the effectiveness of leniency programmes. Similar issues may arise if collusive behaviour in public procurement is criminalised under a statute other than the competition law. Delegations who would like to speak on this topic are invited to contact the Secretariat as soon as possible.

Item VI. (from 15.45 to 16.30). Under this agenda item, WP3 delegates will continue the discussion started last February on *"Remedies for consummated and non-notifiable mergers"*. Delegations who would like to speak on this topic are kindly asked to contact the Secretariat as soon as possible.

Item VII. (from 16.30 to 16.45). The next meeting of WP3 will be held on 28 October 2014 and delegates are asked to decide on the agenda for that meeting and for the February 2015 meeting.

The following two topics have already attracted significant support in the discussion on future work that took place last February: the "*Use of Markers for Cartel Leniency Programmes*" and the "*Relationship between Public and Private Enforcement*". There have been suggestions that the Roundtable on the "*Use of Markers for Cartel Leniency Programmes*" should take place in October 2014, and that the Roundtable on the "*Relationship between Public and Private Enforcement*" would be more suitable for the WP3 meeting in February 2015.

In addition, WP3 will continue its work under the long-term work stream on international co-operation benefitting from the outcome of the June 2014 Hearing.

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Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development **03-Jun-2014**

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DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE

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DRAFT AGENDA OF THE 121st MEETING OF THE COMPETITION COMMITTEE

18-19 June 2014

The 121st Meeting of the Competition Committee will be held on 18-19 June 2014 in Room 1 of the OECD Conference Centre, 2 rue André Pascal, 75116 Paris

Please contact Ms Patricia Hériard-Dubreuil, Deputy Head of Competition Division, if you have any questions regarding this document. [Tel.: +33 (01) 45 24 91 41; Email: Patricia.HERIARD-DUBREUIL@oecd.org]

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I.	**ADOPTION OF THE DRAFT AGENDA**	DAF/COMP/A(2014)2/REV1
II.	**APPROVAL OF THE DRAFT SUMMARY RECORD OF THE LAST MEETING**	
	-- List of Participants	DAF/COMP/M(2014)1/ANN1
	-- Summary Record of 120th Comp. Committee meeting	DAF/COMP/M(2014)1
	-- Summary Record of the Discussion on Relations with Non-Members	DAF/COMP/M(2014)1/ADD1 **(CONFIDENTIAL)**
	For information:	
	-- Summary of the Discussion on the Role of Competition in Financial Consumer Protection	DAF/COMP/M(2014)1/ANN2
	-- Summary of the Discussion of the RT on Ex Officio Cartel Investigations and the Use of Screens to Detect Cartels	DAF/COMP/M(2013)3/ANN4/FINAL
	-- Executive Summary of the RT on Ex Officio Cartel Investigations and the Use of Screens to Detect Cartels	DAF/COMP/M(2013)3/ANN5/FINAL
III.	**REPORTS BY WORKING PARTIES CHAIRMEN AND CO-ORDINATORS**	
	a) Competition Policy and Regulation	
	Report by Chairman of Working Party No. 2	
	For reference:	
	Draft Factsheet on the Links between Competition and Productivity	DAF/COMP/WP2(2014)13
	b) Co-operation and Enforcement	
	Report by Chairman of Working Party No. 3	
	For reference:	
	Revision of the 1995 Recommendation on International Co-operation	DAF/COMP/WP3(2014)8
	c) UNCTAD	
	Report by the UNCTAD Co-ordinator	

d) ICN

Report by the ICN Co-ordinator

IV. LONG TERM STRATEGIC THEMES

For discussion

a) International Co-operation – Proposed Workplan

-- Secretariat Note — DAF/COMP(2014)19

b) 2nd Work stream to be selected

i) Competitive Neutrality

-- Secretariat Scoping Note — DAF/COMP(2014)17

ii) Intellectual Property Rights

-- Secretariat Scoping Note — DAF/COMP(2014)21

iii) Vertical Restraints

-- Joint Proposal by Australian/Austrian Delegations — DAF/COMP(2014)20

c) Evaluation – possible continuation over 2015

-- Secretariat Scoping Note — DAF/COMP(2014)18

V. ANNUAL REPORTS ON COMPETITION POLICY

-- **Reports to be presented by the Delegates at this meeting:**

Belgium	DAF/COMP/AR(2014)1
Czech Republic	DAF/COMP/AR(2014)2
Denmark	DAF/COMP/AR(2014)3
Finland	DAF/COMP/AR(2014)4
Israel	DAF/COMP/AR(2014)5
Slovak Republic	DAF/COMP/AR(2014)6
Sweden	DAF/COMP/AR(2014)7
Turkey	DAF/COMP/AR(2014)8

and

Brazil	DAF/COMP/AR(2014)9
Colombia	DAF/COMP/AR(2014)10
Latvia	DAF/COMP/AR(2014)11
Lithuania	DAF/COMP/AR(2014)12
Romania	DAF/COMP/AR(2014)13
Russian Federation	DAF/COMP/AR(2014)14

-- **Additional reports for this meeting:**

Canada	DAF/COMP/AR(2014)15
Estonia	DAF/COMP/AR(2014)16
Greece	DAF/COMP/AR(2014)17
Iceland	DAF/COMP/AR(2014)18
Ireland	DAF/COMP/AR(2014)19
Luxembourg	DAF/COMP/AR(2014)20
Mexico	DAF/COMP/AR(2014)21
Poland	DAF/COMP/AR(2014)22
United Kingdom	DAF/COMP/AR(2014)23
United States	DAF/COMP/AR(2014)24

VI. ROUNDTABLE ON COMPETITION AND GENERIC PHARMACEUTICALS

For discussion:

-- Notes by experts

Paper by Mr Scott Hemphill	DAF/COMP/WD(2014)74
Paper by Mr. Romano Subiotto	DAF/COMP/WD(2014)75

-- Notes by Delegations

Finland	DAF/COMP/WD(2014)44
Germany	DAF/COMP/WD(2014)57
Italy	DAF/COMP/WD(2014)50
Japan	DAF/COMP/WD(2014)53
Korea	DAF/COMP/WD(2014)58
Spain	DAF/COMP/WD(2014)54
United Kingdom	DAF/COMP/WD(2014)67
United States	DAF/COMP/WD(2014)51
European Union	DAF/COMP/WD(2014)62

And

Bulgaria	DAF/COMP/WD(2014)43
India	DAF/COMP/WD(2014)72
Russia	DAF/COMP/WD(2014)55
South Africa	DAF/COMP/WD(2014)68
Chinese Taipei	DAF/COMP/WD(2014)56
Ukraine	DAF/COMP/WD(2014)42
BIAC	DAF/COMP/WD(2014)63

For reference:

-- Proceedings of the 2009 Roundtable on Generic Pharmaceuticals: http://www.oecd.org/daf/competition/abuse/46138891.pdf

VII. GLOBAL RELATIONS

i) For information

-- Note by the Secretariat on the 2014 and 2015 Global Forum on Competition	DAF/COMP(2014)15

ii) For discussion

-- Draft Agenda (CONFIDENTIAL)	DAF/COMP/A(2014)2/ADD1

VIII. ANTITRUST COMPLIANCE

For reference

-- 2013 ICC Antitrust Compliance Toolkit: http://www.iccwbo.org/Advocacy-Codes-and-Rules/Document-centre/2013/ICC-Antitrust-Compliance-Toolkit/

-- Promoting Compliance with Competition Law – 2011 Proceedings http://www.oecd.org/daf/competition/Promotingcompliancewithcompetitionlaw2011.pdf

IX. ROUNDTABLE ON AIRLINE COMPETITION

For discussion

-- Background note by the Secretariat	DAF/COMP(2014)14
-- Notes by Experts	
Paper by Mr John Balfour	DAF/COMP/WD(2014)76
Paper by Mr Pablo Mendes de Leon	DAF/COMP/WD(2014)77
-- Notes by Delegations:	
Australia	DAF/COMP/WD(2014)24
Austria	DAF/COMP/WD(2014)35
Canada	DAF/COMP/WD(2014)34
Chile	DAF/COMP/WD(2014)27
Germany	DAF/COMP/WD(2014)79
Hungary	DAF/COMP/WD(2014)33
Iceland	DAF/COMP/WD(2014)45
Israel	DAF/COMP/WD(2014)61
Italy	DAF/COMP/WD(2014)38
Japan	DAF/COMP/WD(2014)46
Korea	DAF/COMP/WD(2014)60
Mexico	DAF/COMP/WD(2014)47
New Zealand	DAF/COMP/WD(2014)29
Norway	DAF/COMP/WD(2014)59
Spain	DAF/COMP/WD(2014)64

Switzerland	DAF/COMP/WD(2014)39
Turkey	DAF/COMP/WD(2014)66
United Kingdom	DAF/COMP/WD(2014)36
United States	DAF/COMP/WD(2014)48
EU	DAF/COMP/WD(2014)28

And

Brazil (CADE)	DAF/COMP/WD(2014)25
Brazil (SEAE)	DAF/COMP/WD(2014)40
Bulgaria	DAF/COMP/WD(2014)26
Egypt	DAF/COMP/WD(2014)32
India	DAF/COMP/WD(2014)71
Indonesia	DAF/COMP/WD(2014)70
Peru	DAF/COMP/WD(2014)49
Romania	DAF/COMP/WD(2014)52
Russian Federation	DAF/COMP/WD(2014)30
South Africa	DAF/COMP/WD(2014)65
Chinese Taipei	DAF/COMP/WD(2014)37
Ukraine	DAF/COMP/WD(2014)31
BIAC	DAF/COMP/WD(2014)69

For reference:

Milken Institute Paper by Mr Severin Borenstein
http://www.milkeninstitute.org/publications/review/2014_5/05-12MR62.pdf

X. OTHER BUSINESS

* * *

Schedule

The provisional schedule for the Competition Committee session is as follows:

Wednesday 18 June: Items I. II. III. IV. V and VI

Thursday 19 June: Items VII, VIII and IX (and possible continuation of item V.)

ANNOTATIONS

Item III.

a) The Chairman of the Working Party No. 2 will report on the meeting of the Working Party held on 16 June 2014.

b) The Chairman of Working Party No. 3 will report on the meeting of the Working Party held on 17 June 2014.

c) The UNCTAD co-ordinator may report on UNCTAD related developments.

d) A report on ICN recent developments will be presented.

Item IV.

a) The Competition Committee agreed in February 2014 that International Co-operation will continue to be one of its two long-term strategic work streams over the 2015-2016 biennum – In June 2014, the delegates will decide on the Committee Workplan regarding this theme, based on a Secretariat proposal.

b) Competition delegates will continue their discussion on the choice of a second long term work stream. As requested in February 2014 to support their decision, the Secretariat has expanded the two existing scoping notes respectively on Competitive Neutrality and on Intellectual Property Rights. In addition, the delegations of Australia and Austria are submitting for delegates' consideration a joint alternative proposition on Vertical Restraints.

c) In February 2014, delegates have also expressed interest for a possible continuation over 2015 of the Evaluation work stream with an ex-post evaluation of a number of enforcement decisions from different jurisdictions. A Secretariat Scoping Note presenting the options, pros and cons, as well as resource implications will help the delegates to decide.

Item V.

Delegates are invited to submit their country report as usual while taking note that only half of them will be presented to the June 2014 Competition Committee meeting. Countries listed in the Agenda will be invited to make an oral presentation at this session. Moreover, oral introductory remarks are not obligatory but if such remarks are made, they should be brief (no more than five minutes) with presenters focusing on one or two important points only.

Item VI.

Competition delegates agreed to hold a roundtable on *Competition and Generic pharmaceuticals* to discuss new competition issues that have arisen since the 2009 Committee roundtable, in particular new potentially anticompetitive strategies developed by pharmaceutical companies as well as analysis and rulings on specific types of infringements. Country contributions (see Chairman Jenny's letter requesting country contributions -- COMP/2014.109) will provide the background to the discussion, to be held on Wednesday **18 June afternoon (3-6 pm).** This roundtable will also benefit from the participation as panellists of Prof. Scott Hemphill (Columbia University) and of Romano Subiotto (partner at Cleary Gottlieb).

Item VII.

i) For information: a brief Secretariat report will present the results of an evaluation by participants of the 2014 Global Forum on Competition (GFC) as well as the topics for the 2015 GFC. Invitations to participants including a draft agenda will be extended by the Secretariat after the June Committee meeting.

ii) For discussion: the Committee will continue its discussion in a confidential session – see separate confidential agenda.

Item VIII.

The International Chamber of Commerce (ICC) produced in 2013 an Antitrust *Compliance* Toolkit to complement materials produced by antitrust agencies and other sources of guidance, focusing on practical steps companies can take internally to embed a successful compliance culture. Competition delegates will have the opportunity on **Thursday 19 June, morning**, to exchange views with some of the experts who contributed to its development. Paul Lugar, as chair of the ICC Competition Commission, Anne Riley of Royal Dutch Shell as chair of the ICC Task Force on Antitrust Compliance and Advocacy and Boris Kasten of Schindler as co-chair of the ICC Task Force will present the toolkit and dialogue with delegates.

Item IX.

Delegates will recall that the Committee decided to hold a roundtable on *Airline Competition*. A Background Paper by the Secretariat and country contributions (see Chairman Jenny's letter requesting country contributions -- COMP/2014.25) will provide the background to the discussion, to be held on **Thursday 19 June** (given its broad scope, starting before lunch and continuing in the afternoon). This roundtable will benefit from the participation of Prof. Severin Borenstein (University of California at Berkeley), John Balfour (partner Clyde & Co. -- UK), Professor Pablo Mendes de Leon (Leiden University) and Brian Pearce, Chief Economist at IATA.

Item X.

The Committee will review its work plan for October 2014 and February 2015. Competition delegates have already agreed on two roundtable discussions in October 2014 respectively on i) Standard setting process and on ii) Institutional Design of Competition Authorities (lessons learnt from countries' experience). In addition an Accession review of Latvia will be carried out at that session. The Committee will have to decide on a substantive topic for its February 2015 session.

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

04-Jun-2014

English - Or. English

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE

DAF/COMP/WD(2014)56
Unclassified

GENERIC PHARMACEUTICALS

-- Note by Chinese Taipei --

18-19 June 2014

This document reproduces a written contribution from Chinese Taipei submitted for Item VI of the 121st meeting of OECD Competition Committee on 18-19 June 2014.

More documents related to this discussion can be found at http://www.oecd.org/daf/competition/generic-pharmaceuticals-competition.htm.

JT03358666

English - Or. English

1. This paper will outline the development of generic pharmaceuticals in Chinese Taipei, and address the competition issues and cases of generic pharmaceuticals that have been investigated by the Fair Trade Commission (FTC), as well as court rulings. In preparing this paper, the FTC has consulted the central competent authority of health, the Ministry of Health and Welfare (MOHW), and the patent office, the Intellectual Property Office (IPO) of the Ministry of Economic Affairs (MOEA), to obtain relevant information, and has referred to rulings of the Intellectual Property Court.

1. Overview of Generic Pharmaceuticals in Chinese Taipei

2. In Chinese Taipei, pharmaceuticals should go through the process of Drug Review and Registration, and can only be manufactured, imported or distributed after being granted a permit. The review process emphasizes safety, efficacy and quality: the safety review includes a discussion of pharmaceutical toxicity and its adverse effects; the efficacy review involves the evaluation of the therapeutic effect; and the quality review seeks sustainable and stable manufacturing and management. Generic drugs should be consistent with the original patented drugs in terms of ingredients, drug form, therapeutic effect and dosage. They should be considered as the formula and product, to which modifications are made for developing new drugs. Hence, documents regarding their safety and efficacy are not required while applying for the Drug Review and Registration. With respect to quality, applicants are required to submit the standard operational handbook for chemical manufacturing and control (the content should include controls over the physical and chemical properties of raw materials, testing specifications and methods, manufacturing processes and stability tests, etc.). A common practice in many countries is that, for generic drugs, it is not necessary to repeat all the clinical trials regarding the safety and efficacy of their active ingredients. According to international regulations, after development and production generic drugs are subject to bioequivalence tests by taking the original patented drugs as the standard control. The generic drugs and standard control are administered to the same group of subjects under the same conditions. The results should show no statistically significant differences between generic drugs and the standard control in terms of the pharmacological effects or the amount and speed of active ingredients in blood circulation or on the functioning site. The results serve as a major reference for proving the safety and efficacy of generic drugs. Such a procedure is considered adequate for clarifying consumers' concerns about generic drugs.

3. According to the statistics for pharmaceutical permits in 2012, permits for generic drugs in Chinese Taipei accounted for 82.4% of the total, of which permits for domestically made generic drugs made up 89.6% and those for imported ones the remaining 10.4%. As revealed by the data in past years, about 70% of NHI drugs are domestically-made generic drugs. Pharmaceutical supply in Chinese Taipei relies mainly on domestic pharmaceutical manufacturers. There are no trading and import barriers, or restrictions on the acquisition of generic drugs.

4. The National Health Insurance (NHI) implemented in Chinese Taipei in 1995 is a single-payer compulsory social insurance plan. The National Health Insurance Administration (NHIA) is the only insurer, and is responsible for providing medical services to all citizens. The NHI neither imposes any restrictions on the use of generic pharmaceuticals nor does it limit daily pharmaceutical expenditure. It also does not offer any financial incentives to the physicians, pharmacists, or consumers who prescribe or use the generic drugs. However, in the event where the physician does not specify that an alternative may not be used, the pharmacist shall use the lower cost pharmaceutical (including generic pharmaceuticals) to reasonably control pharmaceutical expenditure[1].

[1] Article 25, Regulations Governing the NHI Medical Care: "Where a physician does not specify that the prescribed drug or medical device cannot be substituted in a prescription, a pharmacist (assistant pharmacist) may replace the drug with a drug of another brand with the same ingredients, dosage and

1. As the separation of medicine and pharmacy has not yet been popularized in Chinese Taipei's medical market, most major hospitals provide pharmaceutical dispensing services, and directly apply for the reimbursement of pharmaceutical expenditure from the NHIA. Due to the quantity and conditions under which medical institutes procure pharmaceuticals, the actual price of pharmaceuticals will naturally vary and form a gap between the price and NHI payments. This creates the issue of whether medical institutions are making unreasonable profits from pharmaceuticals.[2]

2. Competition between Originator and Generic Drugs

5. As a small economy, there are many domestic pharmaceutical manufacturers in the pharmaceutical market of Chinese Taipei. Exporting pharmaceuticals has proven to be difficult and the manufacturers have relatively small scales of operation with weak research and development capability. Therefore, domestic pharmaceutical manufacturers mainly manufacture generic drugs. According to Paragraph 2, Article 31 of the National Health Insurance Pharmaceutical Benefits and Reimbursement Schedule, which states that the reimbursement price of a generic drug may not be higher than 80% of the reimbursement price of the originator, unfair competition might arise from different reimbursement prices for originators and domestic pharmaceutical manufacturers. In the light of growing expenditure on NHI drugs, the NHIA implemented the "*National Health Insurance Drug Pricing Principles*" and announced the "*Guidelines for the National Health Insurance Drug List and Payment Schemes*," which showed the list of NHI drugs and the prices that would be reimbursed. The NHI drugs and amount of NHI reimbursements are disclosed on the NHIA website. To avoid unnecessary waste and the irrational use of drugs, the NHIA carefully reviews pharmaceutical expenditure, and utilizes cloud computing technology to integrate medical records, which are provided as reference to physicians. All these measures have been intended to improve the quality of medical care and ensure that resources are used rationally. Hence, transparent drug pricing has created intense competition between originator drugs and generic drugs in the medical system.

6. The Biotechnology and Pharmaceutical Industries Promotion Office under the MOEA, which is convened by the Industrial Development Bureau, MOEA, consists of the MOHW (the agency that issues pharmaceutical permits), the Intellectual Property Office (IP agency), and the Bureau of Standards, Meteorology & Inspection (standard-setting agency). The office carries out coordination and discussions regarding legal issues of pharmaceutical manufacturing and marketing, including permits, patents, copyright, or standards. However, the office does not engage in discussions on competition issues.

7. With regard to compulsory licensing, in the event of a national emergency or other major emergencies, the competent authority of the Patent Act, the Intellectual Property Office, should compulsorily license the required patent in accordance with the emergency order or notification of the central competent authority of the target business, and shall notify the patent owner as soon as possible. The Office may apply for compulsory licensing[3] when it determines that compulsory licensing is necessary due to one of the following three conditions:

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contents at the same or lower price, or replace the medical device with specialty material of another brand of the same functional category, and inform the beneficiary."

2 See DAF/COMP/GF/WD(2014)31, page 3-4.

3 Article 87 of the Patent Act.

1. where a patented invention is to be exploited non-commercially for the enhancement of public interest;

2. where a later invention or utility model patent cannot be exploited without infringing upon a prior invention or utility model patent, and where the later invention or utility model patent involves an important technical advancement of considerable economic significance in relation to the prior invention or utility model patent; or

3. where a patentee has committed acts restricting competition or has committed unfair competition acts, for which a judgment has been made by a court of law or a decision has been rendered by the FTC.

8. Furthermore, the Office may approve an application for compulsory licensing in the event that it is in order to aid a country without or with insufficient pharmaceutical manufacturing ability to acquire pharmaceuticals for treating AIDS, pulmonary tuberculosis, malaria, or other infectious diseases. However, this must be under the premise that the applicant could not negotiate licensing within a considerable time period using reasonable business conditions.

3. Pharmaceutical Competition Cases Handled in Accordance with the Fair Trade Act

9. Regarding the possible involvement of originators in restrictive or unfair competition, e.g., issuing patent infringement warnings without proper cause/procedure or using unreasonably low price bids to deter generics from entering the market, the FTC mainly investigates individual cases and does not get involved with the overall industry's pharmaceutical prices or permit policy.

10. The FTC investigated a case in which an originator distributor tendered to supply pharmaceuticals at a price far below its purchasing cost to drive out competitors. This act of restrictive competition and preventing fair competition was a violation of the FTA, and the distributor was fined NT$ 3 million.[4] The FTC also investigated several complaints filed by generic drug companies alleging that the originator drug manufacturer issued patent infringement warning letters to their trade counterparts that might violate the FTA. These cases involved the proper exercise of patent rights and the FTC did not find any originator drug companies in violation of the FTA after carefully reviewing these cases.

11. The FTC also investigated some complaints filed by originator drug companies alleging that generic drug companies violated the FTA by imitating the appearance and the package insert (prescribing information or patient information leaflet) of their products. For example, Pfizer Inc. reported to the FTC that the generic drug "Nova" manufactured by Yuanchou Chemical & Pharmaceutical Co. had the same ingredients as their patent drug "Norvasc," and used the same text format and color as well as the oval-shaped word "fine" with similar size and shape. The originator claimed that this would cause confusion among consumers and was in violation of Article 20[5] and Article 24[6] of the FTA. After investigating the

4 See DAF/COMP/GF/WD(2014)31, page 6-7.

5 Paragraph 1, Article 20 of the Fair Trade Act: No enterprise shall have any of the following acts with respect to the goods or services it supplies:

(1) using in the same or similar manner, the personal name, business or corporate name, or trademark of another, or container, packaging, or appearance of another's goods, or any other symbol that represents such person's goods, commonly known to relevant enterprises or consumers, so as to cause confusion with such person's goods; or selling, transporting, exporting, or importing goods bearing such representation;

(2) using in the same or similar manner, the personal name, business or corporate name, or service mark of another, or any other symbol that represents such person's business or service, commonly known to

case, the FTC decided that the two products would not cause confusion to consumers and the generic drug company did not violate the FTA.

4. Civil Cases Related to Competition between Originator Drugs and Generic Drugs

12. The number of civil cases between originators and generics has shown an upward trend in recent years. After an originator drug company's patent expires, the company often files infringement lawsuits against generic drug companies, claiming to protect their "pharmaceutical patent" and "package insert copyright," but actually intending to maintain their monopoly in the market. Generic drug companies have also filed civil lawsuits for damages to their rights.

Case 1: Genovate Biotechnology Co., Ltd. vs. Takeda Pharmaceutical Industry Ltd.

13. Genovate Biotechnology Co. filed a lawsuit with the intellectual property court. The company had applied to the MOHW for a pharmaceutical permit and to conduct clinical trials for their product Vippar (oral diabetes medication), which contains "pioglitazone," a prescription drug that they developed. Takeda Pharmaceutical Industry Ltd. knew that it does not own the patent to "pioglitazone," but falsely claimed that it did to Taichung District Court in 2004, and requested a provisional injunction against Vippar for infringing its invention patent No.135500 "pharmaceutical compositions for preventing and treating diabetes." The provisional injunction was approved and executed by the court. This led to the MOHW delaying the issuance of Vippar's pharmaceutical permit and prevented its legal sales, pushing back the time when the product entered the market and causing Genovate to sustain damages. Genovate Biotechnology claimed that Takeda Pharmaceutical engaged in unfair competition via the court's securitization proceedings to maintain the monopoly of Actos, the patent drug manufactured by Takeda Pharmaceutical, because clinical trials of Vippar would severely threaten the market share and price of Actos. This is a violation of the FTA and Genovate Biotechnology thus sought civil compensation in accordance with the law.

14. The case was tried in the Intellectual Property Court for the first instance, and the court ruled in favor of the defendant, finding that Takeda Pharmaceutical followed the proper procedure of the Patent Act and did not engage in unfair competition. Genovate Biotechnology appealed and in the second instance Takeda Pharmaceutical admitted that Vippar had the same ingredients as Actos, and that it claimed that the clinical trials and application for a pharmaceutical permit for Vippar infringed its patent, even though it was aware that invention patent No.135500 "pharmaceutical compositions for preventing and treating diabetes" did not include patent rights over the ingredient of the drug, "pioglitazone." The provisional injunction filed by Takeda Pharmaceutical was granted and prevented Vippar from entering the market for several years, allowing Takeda Pharmaceutical to gain additional profit without any competition with Actos. The legal action taken by Takeda Pharmaceutical was a means to preventing a competitor's product from entering the market, and the abuse of this right affected fair trade, which was a violation of Article 24 of the FTA. Takeda Pharmaceutical was thus liable for any damages in accordance with Articles 31 and 32 of the FTA[7]. The court of second instance ruled in December 2010 that Takeda Pharmaceutical should

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relevant enterprises or consumers, so as to cause confusion with the facilities or activities of the business or service of such person; or

(3) using on the same or similar goods the mark that is identical or similar to a well-known foreign trademark that has not been registered in this country; or selling, transporting, exporting, or importing goods bearing such trademark.

6 Article 24 of the Fair Trade Act: In addition to what is provided for in this Law, no enterprise shall otherwise have any deceptive or obviously unfair conduct that is able to affect trading order.

7 Article 31 of the Fair Trade Act: Any enterprise that violates any of the provisions of this Law and thereby infringes upon the rights and interests of another shall be liable the damages arising therefrom.

compensate Genovate Biotechnology NT$50 million in accordance with the FTA and Code of Civil Procedure, and should pay annual interest of 5% starting on April 22nd, 2009 until the debt was paid off. Although Takeda Pharmaceutical appealed to the Supreme Court, its appeal was dismissed on February 23rd, 2012 and the ruling was made final.

Article 32 of the Fair Trade Act: In response to the request of the person being injured as referred to in the preceding article, a court may, taking into consideration of the nature of the infringement, award damages more than actual damages if the violation is intentional; provided that no award shall exceed three times of the amount of damages that is proven.

Where the infringing person gains from its act of infringement, the injured may request to assess the damages exclusively based on the monetary gain to such infringing person.

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

03-Jun-2014

English - Or. English

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE

DAF/COMP/WD(2014)37
Unclassified

AIRLINE COMPETITION

-- Note by Chinese Taipei --

18-19 June 2014

This document reproduces a written contribution from Chinese Taipei submitted for Item IX of the 121st meeting of OECD Competition Committee on 18-19 June 2014.

More documents related to this discussion can be found at http://www.oecd.org/daf/competition/airlinecompetition.htm.

JT03358580

English - Or. English

1. This paper will outline the state of and regulation measures for the air transport market in Chinese Taipei. It also discusses competition issues of the industry and cases investigated by the Fair Trade Commission (FTC). To prepare this paper, the FTC consulted with the Civil Aeronautics Administration (CAA), the central competent authority, and the Institute of Transportation, both of the Ministry of Transportation and Communications (MOTC).

1. The state and regulation of the air transport market in Chinese Taipei

2. The air transport market in Chinese Taipei is divided into two main categories: international and domestic. As of April 30, 2014, there have been eight airlines[1] registered under Chinese Taipei, of which two[2] are running international air route service, four[3] are running international and domestic air route service, and two[4] are running helicopter carrier service or domestic offshore and outlying islands air route service. In light of the rapid rise of the international low-cost carrier industry, the MOTC of Chinese Taipei, in an effort to promote the evolvement of the low-cost carrier industry, amended laws in 2013 that lowered the threshold for entry applications. So far two airlines have been granted permission to be low-cost carriers, which are under progress. In 2013, the international and inter-Taiwan-Strait passenger traffic reached 38.27 million person-times, of which 58.28 percent was accounted as airlines registered in Chinese Taipei. In 2013, the volume of international and inter-Taiwan-Strait air freight reached 1.64 million metric tons, of which 41.61 percent was accounted as airlines registered in Chinese Taipei. In terms of individual airlines, China Airlines led the pack with a 32.99 percent market share, compared to Eva Air with 22.48 percent. It is worth pointing out that China Airlines joined the Sky Team airline alliance in September 2011 and Eva Air joined the Star Alliance in June 2013.

3. Having adopted an "open sky" policy since 1987, Chinese Taipei has basically deregulation on air fares and flights, giving businesses the flexibility to adjust their prices (fares) and quantities (flights) according to business needs and market demands. However, route acquisitions, given restrictions on quotas and available time slots at airports, remain under heavy regulation. The regulation measures adopted by the civil aeronautics competent authority in Chinese Taipei include:

1. Restrictions on applications by a civil air transport enterprise for permission to establish its business. Article 48 of the Civil Aviation Act (CAA) stipulates that a civil air transport enterprise shall obtain permission from the competent authority to establish its business and during the preparatory period its operational plan should pass inspection. Only after receiving a license from the CAA may the enterprise begin to operate.

2. Restrictions on applications for flights. Article 50 of the CAA stipulates that a civil air transport enterprise should have secured international air traffic rights with relevant slots and be in possession of an air route certificate before it can engage in international scheduled air transport service on assigned air routes. Likewise, a civil air transport enterprise should have acquired aircraft takeoff and landing allotments for domestic airports or slots and be in possession of an air route certificate, prior to commencing domestic scheduled air transport service on designated air routes.

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1 China Airlines, Eva Air, TransAsia Airways, Far Eastern Air Transport, Mandarin Airlines, UNI AIR, Daily Air Corp., and Sunrise Airlines were registered under Chinese Taipei.

2 China Airlines and Eva Air were registered under Chinese Taipei.

3 TransAsia Airways, Far Eastern Air Transport, Mandarin Airlines, and UNI AIR were registered under Chinese Taipei.

4 Daily Air Corp. and Sunrise Airlines were registered under Chinese Taipei.

3. Restrictions on ticket prices. Article 55 of the CAA stipulates that a civil air transport enterprise engaging in domestic scheduled air passenger or cargo services shall apply for permission as to the ceiling and floor of its fares. A civil air transport enterprise shall notify the competent authority regarding its fares for passengers and cargo services on scheduled international air routes. The fares are the ceilings. In addition, the MOTC has issued *Regulations Governing Tariffs for Passengers and Cargo Air Transportation* to regulate the fares on scheduled flights for passengers or cargo.

4. Restrictions on alliances. Article 58-1 of the CAA stipulates that civil air transport enterprises shall receive approval from the MOTC before undertaking alliance operations. An alliance shall be subjected to approval from the FTC if the alliance meets the scope of concerted actions under Article 7 of the Fair Trade Act (FTA). The Reviewing Rules for Approving the Alliance shall be promulgated by the MOTC together with the FTC.

2. Market competition in the airline industry: market definition, cartel agreements, mergers, abusing market dominance, financial difficulties, and competition

2.1 Market definition

4. Article 5 of the FTA stipulates that the term "relevant market" means a geographic area or a coverage wherein enterprises compete in respect to particular goods or services. "A geographic area or a coverage" shall include the combination of all goods or services that can reasonably substitute for each other in price, quality, and other functions to satisfy specific needs. Based on Point 4 of the "*Principles for the Fair Trade Commission to Handle the Merger and Alliance of Domestic Civil Aviation Enterprises"* and internationally generally accepted definitions for air transport markets, Chinese Taipei adopts the city-pair as the smallest unit of a market while also taking into account the following factors: 1) the substitutability of routes whose origin and destination combinations are in close proximity; 2) the substitutability among transport vehicles in the air, high-speed rail, rail, highways, and waterways; and 3) other factors relevant to the definition of aviation markets. The assessment of substitutability among the above-mentioned transport vehicles among different routes shall take into account the following factors: 1) travel distance and length of time; 2) passenger characteristics and time cost of travel; and 3) the ability of service providers to collectively or individually make small but significant and non-transitory increase in price without impacting their profitability.

2.2 Cartel agreements, mergers and abusing market dominance

5. Chinese Taipei in principle prohibits cartel agreements, to which it grants permission only on an exceptional basis. As for mergers, it only regulates merger cases of enterprises exceeding a certain scale threshold. The enterprises concerned must submit applications to the FTC in advance of forming the mergers. The FTC has issued the "*Principles for the Fair Trade Commission to Handle the Merger and Alliance of Domestic Civil Aviation Enterprises"* so it may effectively review applications for alliances and mergers from enterprises engaging in air transport so as to maintain market order and consumer rights and to ensure fair competition. Point 4 of the "*Regulations on the Examination of Applications for Alliances of Enterprises Engaging in Civil Aviation"* stipulates that "code sharing, the transferring of ticket coupons without endorsements, co-promotions, and other alliance operations that are sufficiently capable of impacting the production, commercial transactions, or the supply and demand of the market" shall be deemed as concerted actions under Article 7 of the FTA, and as such, shall be allowed only with prior approval from the FTC. As for the abuse of market dominance, the FTC has yet to handle a penalty case against any enterprise in civil aviation for abusing its market dominance in Chinese Taipei.

2.3 Financial difficulties and competition

6. On an exceptional basis, Article 14(6) of the FTA allows "joint acts limiting the quantity of production and sales, equipment, or prices for the purpose of meeting the demand orderly, while in economic downturn, the market price of products is lower than the average production costs so that the enterprises in a particular industry have difficulty in maintaining their business or encountering a situation of overproduction". Accordingly, enterprises engaging in civil aviation may apply to the FTC for permission to conduct joint acts on an exceptional basis.

3. Case example 1: TransAsia Airways and UNI AIR signed a revenue pool agreement for the Kaohsiung-Kinmen and Kaohsiung-Magong routes in violation of the FTA (2008)

7. According to the Civil Aviation Act, for those airline companies intend to form a alliance operation, they "shall file request to the MOTC through CAA for approval." Also, they have to apply for approval from the FTC as it involves concerted action. The two companies, TransAsia Airways and Uni AIR, signed the revenue pool agreement for the routes Kaohsiung-Kinmen and Kaohsiung-Magong without applying for approval either from the CAA or from the FTC. .

8. The Kaohsiung-Kinmen and Kaohsiung-Magong routes are for remote islands with no on-land substitutes available. Ferry services and the services offered by the air routes in this case differ markedly in transport volume, pricing, and travel time. Take the Kaohsiung-Magong route as an example, the vessel Tai Hwa offers one or two daily trips, the fare is a mere NT$860, and the trip takes about four to six hours one way. These factors make the sea route markedly different from the air route. Therefore, the case adopted the city-pair, i.e. Kaohsiung-Kinmen and Kaohsiung-Magong air transport routes, as the market.

9. The FTC investigation revealed that the Kaohsiung-Kinmen and Kaohsiung-Magong air routes were served only by TransAsia Airways and UNI AIR, making the two companies horizontal competitors. The two companies signed the "revenue pool agreement" on November 4, 2003, which specified the number of seats they would supply to the said routes in a week and how they would split the revenue. They operated the routes jointly and shared the profit by entering into such an agreement. They engaged in concerted action given: 1) that the parties engaging in the alliance held a 100 percent market share, 2) that the said agreement, specifying percentages of airplane seats supplied by the parties and their shares of the proceeds, would lower the willingness of the parties to offer more favorable price or non-price conditions to attract customers, and 3) that there were no competitors, the action of the said parties was sufficient to affect the market function of commodity transactions or the supply of and demand for services.

10. The FTC concluded that the "revenue pool agreement" that TransAsia Airways and UNI AIR signed to specify the percentage of airplane seats and how they would settle the proceeds constituted a concerted action that mutually restricted business activities sufficiently capable of affecting the market function of the supply of and demand for air transportation on the Kaohsiung-Kinmen and Kaohsiung-Magong air routes. Such an act was in violation of Article 14(1) of the FTA. The FTC ordered the two companies to immediately cease the unlawful act and imposed an administrative fine of NT$1,000,000 respectively.

4. Case example 2: The approval of the application from Far Eastern Air Transport, Mandarin Airlines, TransAsia Airways, and UNI AIR for a concerted action to transfer ticket coupons without endorsements for the Taipei-Kaohsiung air route (2007)

11. The four participants in the concerted action in this case held a 100 percent market share in the air transport market for the Taipei-Kaohsiung air route. The parties applied for permission to implement the Taipei-Kaohsiung air route "transfers of ticket coupons without endorsements," which would enable

consumers to use a valid airplane ticket for the said route to board any flight offered by any of the participants without first being endorsed by the company issuing the ticket. In other words, the validity of such unified Taipei-Kaohsiung air tickets in fact had the effect of increasing the liquidity of airplane tickets, thereby making it more convenient for passengers to fly, and increasing seat occupancy rates for the airlines. The action was beneficial to the operational efficiency of the airlines, and so this case satisfied the requirement of Subparagraph 1 of Article 14(1) of the FTA.

12. Article 14 of the FTA clearly stipulates that a concerted action can be approved as an exception only when it is "beneficial to the economy as a whole and in the public interest". The FTC considered that the proposed concerted action was beneficial to the economy as a whole and in the public interest because 1) consumers benefit from a shortened wait for flights, 2) airlines benefit from improved efficiency as a result of increased seat occupancy rates, 3) lowered costs of flying enhance the efficiency of resource utilization, and 4) the central competent authority, the MOTC, offered a favorable opinion. The FTC also considered that the concerted action did not restrict competition or result in disadvantages from unfair competition because 1) it did not cause significant market entry barrier, 2) it had a limited effect on price rigidity, 3) it did not lower the incentives for the airlines to provide innovative services, 4) it did not impact the upstream and downstream markets, and 5) it did not apparently and negatively diminish the rights of consumers. After considering these factors, the FTC, pursuant to Article 15 of the FTA, attached conditions to address concerns that the proposed concerted action may subsequently cause restricted or unfair competition and to ensure that the proposed concerted action would bring about results that are "beneficial to the economy as a whole and in the public interest". Based on the proviso in Article 14(1) of the FTA, the FTC granted permission for the proposed concerted action for a period of two years.

13. The conditions attached to the approval were as follows: 1) To address concerns about the effect on price rigidity, two conditions were attached: "the applicants may not without reasonable justification prevent others from withdrawing from or renegotiating the terms in the 'Agreement for air ticket transfers without endorsement' about the settlement of the proceeds," and "in addition to issuing and selling airplane tickets that can be transferred without endorsement for the Taipei-Kaohsiung air route, the applicants shall issue and sell non-transferable airplane tickets that are subject to market competition mechanisms and price competition." 2) To address concerns about market entry barrier, the FTC attached this condition: "the applicants may not without reasonable justification prevent other enterprises from joining this concerted action under reasonable conditions." 3) To address concerns about the applicants engaging in other concerted actions as a result of this concerted action, the FTC attached this condition: "Each applicant shall make its own independent decisions about the prices and other terms of transaction for its transport service on the Taipei-Kaohsiung air route. Under the approval of this concerted action, the applicants may not enter into agreements by contract, accord, or otherwise to jointly set the prices and other transaction conditions for the air transportation on the Taipei-Kaohsiung route." 4) To ensure that this concerted action brings about positive benefits, the FTC attached this condition: "During the permission period of this concerted action, if the applicants reduce their flights for the Taipei-Kaohsiung air route, the reduction may not exceed 20 percent of the approved flights at the time of the approval of this concerted action." 5) To monitor whether or not the conditions attached to this concerted action have been adhered to and whether or not the economic condition at large has changed, the FTC attached these undertakings: "Every six months, the applicants shall submit their transaction data about the concerted action on the Taipei-Kaohsiung air route to the FTC for reference; the data shall include the pre-agreed amounts of settlement, the net amounts of actual settlement between two parties, passenger seats offered, number of passengers on board, seat occupancy rates, published fares, average sale unit price, amount of total sales, and the ratio of sales between transferable and non-transferable tickets."

14. Taiwan High Speed Rail (THSR) was inaugurated in 2007. In that year, the Taipei-Kaohsiung air route, which was served by four airlines registered under Chinese Taipei, logged 1.335 million passenger-times. Three fourths of that market fell in 2008, forcing three airlines to withdraw from the market. The

market further declined to just more than 25,000 passenger-times in 2009. After five years of hard struggle against the high-speed rail, the Taipei-Kaohsiung air route was shut down in September 2012.

5. Case example 3: Domestic civil aviation businesses collectively reduced flights in violation of the FTA (2000)

15. Due to apparent declines in seat occupancy rates and in an attempt to lower operational costs and relieve financial stress, four airlines registered under Chinese Taipei, by agreement, started in May 2000 to unanimously and jointly reduce the supply of domestic flight services. The act was in violation of Article 14 of the FTA and was punished in a ruling of the 473rd meeting of FTC Commissioners on November 30, 2000. However, the FTC's decision was repealed by the appeal council in the Executive Yuan for the following reasons. The seat occupancy rates of airlines have continually declined since 1996, resulting in excess capacity and mounting losses for the airlines. Out of consideration for operating costs and the relief of aviation management, the CAA had encouraged the airlines to take the initiative to reduce their flights and, on unofficial occasions, had also required the airlines to take the initiative to reduce flights. In light of the fact that the four airlines reduced their flights at the request of the CAA and that it had agreed to the reduced flight schedules, did the unanimous action of these airlines constitute an intent to engage in a concerted action? In addition, was the degree of reduction sufficient to affect market supply and demand mechanisms? These questions remain to be investigated, and the original decision by the FTC was repealed.

16. It should be pointed out that the position of the CAA on this case during the FTA investigation was inconsistent with that during the appeal process. During the investigation of the case, the CAA indicated that 1) the flight adjustments that the airlines made in May 2000 were spontaneous acts that they had undertaken according to their fleet capacity and market demand, and 2) the CAA had not invited the airlines to conduct discussions or engaged in moral persuasion. However, during the appeal process of the case, the CAA changed its stance to indicate that, out of consideration for operating costs and for the relief of aviation management, it had, as a matter of its long-held policy, encouraged the airlines to take the initiative to reduce their flights and, on unofficial occasions, it had also required the airlines to take the initiative to reduce flights. The FTC subsequently decided that the act in question that the four airlines had undertaken, based on the evidence available at the time, could not be ruled as being in violation of the FTA.

6. Conclusions

17. After opening the air transport market to competition from the low-cost carriers under the "open sky" policy, the competition among airlines in Chinese Taipei will intensify, giving rise to strong competitive pressure. Therefore, strategic alliances or cooperation among airlines will only intensify. Will strategic alliances or cooperation among airlines bring about anti-competition results, or will they be considered as acts involving mergers or concerted actions under the FTA? Therefore, the FTC will review or conduct research on the current development of strategic alliances in the civil aviation industry, operational models, and their negative impacts on market competition. It will also review civil aviation laws and policies in Chinese Taipei, market structure, the state of competition, and changes in other economic and social factors to make timely amendments to the "*Principles for the Fair Trade Commission to Handle the Merger and Alliance of Domestic Civil Aviation Enterprises"*. In addition, the FTC will continue to monitor competition issues in the marketplace, including business mergers, alliances, agreements on ticket prices or ticket matters, concerted reductions in flights, joint plans, or even the allocation of takeoff and landing times and the arrangement of flight schedules.