Comment on proposal by several countries to add language clarifying references to MAT or VMAT on the transfer of technology or know-how is without prejudice to other measures

KEI Briefing Note 2024:2A

James Love

Knowledge Ecology International (KEI)
May 21, 2024

Introduction

An important issue in the pandemic agreement as well as other global negotiations concerning access to health care and development in general are those relating to the transfer of technology.

The transfer of technology can involve a variety of measures, particularly for complex medicines with challenging regulatory pathways. Licenses to use patented inventions are one mechanism, but other measures may include such topics as access to manufacturing know-how and materials used in manufacturing, such as working cell lines, as well as rights to access and rely upon information from regulatory filings.

Most technology transfer takes place through voluntary agreements, but as noted in the pending EU regulation on compulsory licensing in emergencies, there are times when voluntary measures are not adequate or available. In such cases, governments can and sometimes do use a variety of measures to compel technology transfer.

In the various INB drafts, the terms "mutually agreed terms," referred sometimes as MAT, often appear following references to the transfer of technology or manufacturing know-how, although in some earlier INB drafts the terms disappeared completely. It is known that G7 countries (Canada, France, Germany, Italy, Japan, the United Kingdom and the United States), Switzerland and the European Commission have insisted on including not only MAT in the text, but also more recently, to add the term voluntary, now referred to by negotiators as VMAT.

Following extensive industry lobbying efforts, the phrase mutually agreed terms has increasingly been inserted in various UN negotiations in connection with technology transfer, but much less common is the VMAT formulation. In the WTO TRIPS Agreement MAT is never used in connection with technology transfer, but is used twice in the context of negotiations between Members on technical cooperation.

On May 2, 2024, the UN General Assembly rejected an amendment by Switzerland to insert VMAT into a paragraph on technology transfer in a resolution on global health. (See discussion from an article by Arianna Schouten on the vote, excepted below).

We have criticized the extensive references to MAT in the pandemic agreement as providing a misleading narrative that suggests that transfers of know-how and other elements of technology transfer can only be done through negotiations with companies, and that governments should refrain from regulating companies by mandating transfers, or attaching take-it-or-leave terms in contracts involving R&D or procurement. (See the detailed discussion in "KEI comments on six references to "mutually agreed terms" in the WHO pandemic agreement negotiating text: A/INB/9/3 Rev.1, 22 April 2024," April 28, 2024, https://www.keionline.org/39741).

There are plenty of examples of mandates to transfer manufacturing know-how in the United States, Europe and other countries.

In the current WHO negotiations, we have encouraged negotiators to look at recitals 32a and 32b of the proposed European Union regulation on compulsory licensing in emergencies, which makes it clear that compulsory non-voluntary measures can be used for trade secrets, manufacturing

know-how, biologic resources and other inputs necessary to manufacture countermeasures in an emergency.

We also have also called attention to the extensive use of the U.S. Defense Production Act for COVID-19 and other situations, and highlighted key parts of the legislation relating to manufacturing know-how and materials. (See discussion of Article 11 in KEI Comments on the May 10, 2024 INB Draft of the Pandemic Accord, May 17, 2024, https://www.keionline.org/39978).

Below are a few more examples of how mandates on technology transfer are used or proposed in the United States, including a legislative proposal on mandates for technology transfer for drugs and biologic products in a bill with 79 cosponsors in the House of Representatives.

Attempts to insert “without prejudice to other measures” into the IHR and INB texts

In discussions with negotiators from some G7 nations, I was told they were operating under high level instructions to get at least MAT into the text, and VMAT if possible. I propose that if MAT or VMAT makes it into the text in the content of technology transfer, they had a moral obligation to make it clear that it only applied to various promises to promote or incentivize technology transfer, and did not create any norms that would prevent a country from using measures of a regulatory or mandatory nature, because since the US and the EU were also clear that they did not think anything in the draft would prevent them from using mandatory measures. We did not want language in a WHO agreement on pandemics to be used to bully developing countries into accepting a double standard on technology transfer, ironically in an agreement originally priming to bring about more equity.

I had earlier suggested that in the context of technology or knowledge transfers, whenever MAT is used, to add “without prejudice to other measures a Party may take on technology transfer of a regulatory or mandatory nature.” I was told by negotiators that any reference to mandatory in connection with technology transfer would be blocked. A shorter version was proposed by Brunei, as “without prejudice to any other measures a Party may take,” which is now in the May 10, 2024 text as “without prejudice to other measures a Party may take.”

Some high-income countries argued that “other measures” was too open ended, and proposed that the language be something like “without prejudice to flexibilities that WTO Members have under the provisions of the TRIPS Agreement.”

The IHR proposals

In a May 17, 2024 negotiation on the IHR, the United States proposed the following language on a similar provision in a footnote to Article 13.8(e) that would come right after "mutually agreed terms."

> “For greater certainty, the reference to voluntary transfer of technology, know-how and expertise on mutually agreed terms is without prejudice to the rights, obligations, and flexibilities that WTO Members have under the provisions of the TRIPS Agreement, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health."

This formulation was too restrictive, because while the TRIPS Agreement does address some technology issues, particularly those relating to patented inventions and confidential information and regulatory data, it does so in the sense of providing rights in inventions and confidential information with certain exceptions to the protection, but it does not address measures to require pro-active knowledge sharing or access to materials such as cell lines, measures that are available to the USA, the European Union members, and other Parties.

However, after some back and forth between negotiators, a small change was made to the proposed footnote, and it was co-sponsored in the IHR negotiations by the US, the UK, Brazil and Colombia, and read:

> "For greater certainty, the reference to voluntary transfer of technology, know-how and expertise on mutually agreed terms is without prejudice to other measures that Parties may take consistent with the rights, obligations, and flexibilities that WTO Members have under the provisions of the TRIPS Agreement, including those reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health."

By making the reference to TRIPS so that the measures are consistent with TRIPS, as opposed to only those flexibilities in the TRIPS, this revision made the language more inclusive.

In the IHR negotiations, several developing countries asked for additional changes, and therefore the footnote is in brackets, and may or may not survive if it does not get consensus. The current IHR language is as follows:

> ALT
> [FN “For greater certainty, the reference to [voluntary transfer of technology, know-how and expertise on] mutually agreed terms [applies only in the context of technology licensing agreements] is without prejudice to other measures that States Parties may take[, including those] consistent with the rights, obligations, and flexibilities that WTO Members have under the provisions of the TRIPS Agreement, including those reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health." USA, UK, BRA, COL]

KEI Recommendation

The proposal by the USA, UK, BRA and COL for a footnote in the IHR is welcome. Of course, the language could be better, and particularly, more clear that the other measures may include those of a regulatory or mandatory nature. But that said, it is really a significant proposal that KEI supports.

> "For greater certainty, the reference to voluntary transfer of technology, know-how and expertise on mutually agreed terms is without prejudice to other measures that Parties may take consistent with the rights, obligations, and flexibilities that WTO Members have under the provisions of the TRIPS Agreement, including those reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health."

It is our understanding that the G7 countries would support the following language for the INB, to apply to the entire agreement. KEI also supports this proposal:

> "For greater certainty, for the purposes of this Agreement references to the transfer of technology or know-how on voluntary and mutually agreed terms are without prejudice to other measures that Parties may take consistent with the rights, obligations, and flexibilities that WTO Members have under the provisions of the TRIPS Agreement, including those reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health."

It is our understanding that this will be the first time that a mention of MAT or VMAT is followed by a clarification that parties are not bound by the voluntary or MAT restrictions.

By stating that “voluntary and mutually agreed terms are without prejudice to other measures that Parties may take” the language does something very important, it effectively eliminates the opportunities for the MAT or VMAT language to be misused in the IHR or the Pandemic Agreement in a manner that harms developing countries, and it will be the first time such a clarification have become part of a UN agreement. .

ANNEX, proposed legislation in the United States to mandate the transfer of technology for drugs or biologic products

https://www.congress.gov/bill/117th-congress/house-bill/4811/text

H.R.4811 - Medicare Negotiation and Competitive Licensing Act of 2021
117th Congress (2021-2022)

SEC. 6. MANUFACTURER PROVISION OF INFORMATION.

(a) In General.—In the case of a manufacturer of a drug or biological subject to a competitive licensing agreement under section 1860D–11(i)(5) of the Social Security Act, as added by this Act, such manufacturer shall, upon request from an entity electing to manufacture such drug or

biological, provide to such entity materials, data, and information relating to the manufacture or supply of such drug or biological, including—

(1) cellular clones and hybridoma stocks;

(2) plasmids, plasmid maps, and sequences of antibody complementarity determining regions;

(3) physicochemical and biophysical characterization;

(4) growth conditions and protocols;

(5) attenuation or inactivation protocols;

(6) extraction and purification protocols;

(7) synthetic work-up and schemes;

(8) sufficient quantities of the drug or biological for testing;

(9) the protocols and methods used for testing the drug or biological; and

(10) the expected outcomes from those protocols.

(b) Enforcement.—The Secretary of Health and Human Services may impose a civil monetary penalty on a manufacturer of not more than $10,000 per day for a violation of subsection (a).

ANNEX on UNGA May 2, 2024 rejection of VMAT language in resolution on global health

UN rejects amendment to limit technology transfer to “voluntary and mutually agreed terms” in resolution on global health
Posted on May 3, 2024 by Arianna Schouten
https://www.keionline.org/39781

The New York votes concerned certain paragraphs within draft resolution A/78/L.62, entitled, “Global health and foreign policy: addressing global health challenges in the foreign policy space” that had been originally tabled on April 19, 2024, by Brazil, France, Indonesia, Norway, Senegal, South Africa, and Thailand.

Switzerland offered an amendment that would insert “on voluntary and mutually agreed terms” after “transfer of technology and know-how” in the twenty-ninth preambular paragraph.

Swiss-Amendment.n2412117-1May2024

The proposed amendment to paragraph 29 reads as follows:

PP29: Noting the discussions on innovative options to enhance the global effort towards the production and equitable distribution of medicines and other health technologies through local and regional production, welcoming the establishment of technology transfer hubs for mRNA vaccines to develop and strengthen local and regional production chains in developing countries, and emphasizing the need to enhance the manufacturing and research capacity of countries through innovation and transfer of technology and know-how [add: on voluntary and mutually agreed terms] with the support of developed countries and advance industries;

[On May 2, 2024] Member States then voted, and the amendment was rejected, with 103 UN members voting against the amendment, 49 voting in favor, and three abstentions (India, Mauritius, and Togo).

ANNEX, recitals 32a and 32b of the proposed EU regulation on compulsory licensing in emergencies

Resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (COM(2023)0224 – C9-0151/2023 – 2023/0129(COD)).

> 32a “Where appropriate, the Commission should oblige the rights-holder to disclose the trade secrets which are strictly necessary in order to achieve the purpose of the Union compulsory licence. . . . It is possible that a detailed description of how to carry out the invention might not be sufficient and complete enough to enable the licensee to efficiently use that invention. This could encompass, without being exhaustively limited to, the comprehensive transfer of necessary technology, expertise, data, samples, and reference products essential for production and obtaining market authorisation in collaboration with the licensee. . .
>
> 32b “. . . While patent licensing alone might suffice to enable other manufacturers to quickly produce simple pharmaceuticals, in case of more intricate pharmaceutical products, such as vaccines during a pandemic, it is often insufficient. Where it is essential for the implementation of the compulsory licence, an alternative producer will also require access to know-how.”

Annex: US Defense Production Act, selected definitions in 50 USC 4552

(3) **Critical technology.** The term "critical technology" includes any technology designated by the President to be essential to the national defense.
(4) **Critical technology item.** The term "critical technology item" means materials directly employing, derived from, or utilizing a critical technology.
(6) **Domestic industrial base.** The term "domestic industrial base" means domestic sources which are providing, or which would be reasonably expected to provide, materials or services to meet national defense requirements during peacetime, national emergency, or war.
(8) **Facilities.** The term "facilities" includes all types of buildings, structures, or other improvements to real property (but excluding farms, churches or other places of worship, and private dwelling houses), and services relating to the use of any such building, structure, or other improvement.
(12) **Industrial resources.** The term "industrial resources" means materials, services, processes, or manufacturing equipment (including the processes, technologies, and ancillary services for the use of such equipment) needed to establish or maintain an efficient and modern national defense industrial base.
(13) Materials. The term "materials" includes—
(A) any raw materials (including minerals, metals, and advanced processed materials), commodities, articles, components (including critical components), products, and items of supply; and
(B) any technical information or services ancillary to the use of any such materials, commodities, articles, components, products, or items.

The US Defense Production Act was used extensively by the US government during the COVID-19 Pandemic.

See:

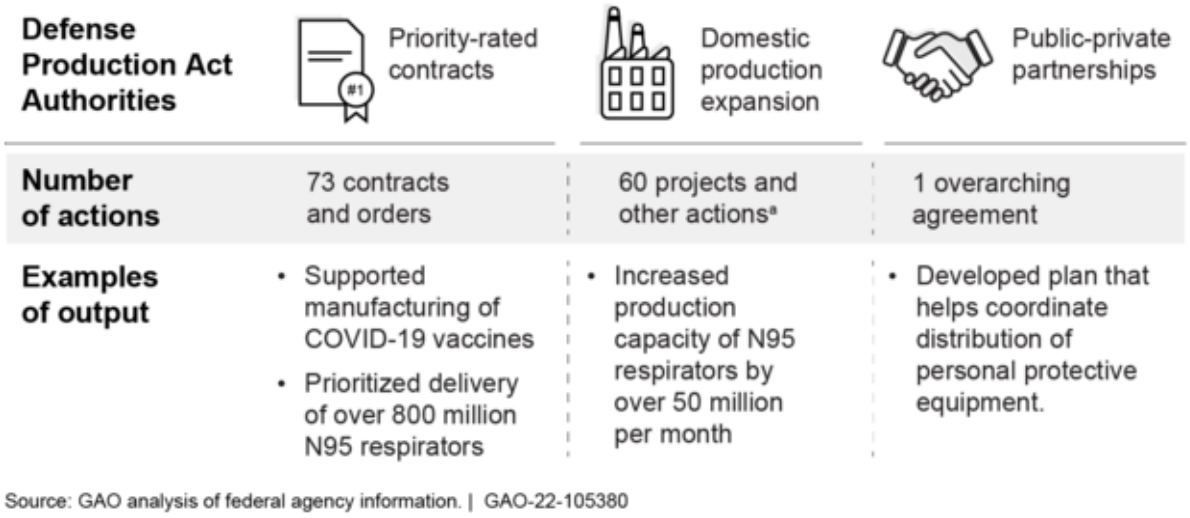
Defense Production Act: Opportunities Exist to Increase Transparency and Identify Future Actions to Mitigate Medical Supply Chain Issues: GAO-21-108, Published: Nov 19, 2020. Publicly Released: Nov 19, 2020. https://www.gao.gov/products/gao-21-108

COVID-19: Agencies Are Taking Steps to Improve Future Use of Defense Production Act Authorities, GAO-22-105380, Published: Dec 16, 2021. Publicly Released: Dec 16, 2021. https://www.gao.gov/products/gao-22-105380

Among the U.S. Government Accountability Office (GAO) Findings:

> “Federal agencies used the Defense Production Act (DPA) and other actions over 100 times to help address COVID-19 medical supply needs through September 2021. Agencies used DPA authorities to 1) prioritize contracts so those orders can get preference over others, (2)

fund projects to expand domestic production of supplies, and (3) enter into partnerships with private companies (see figure)."



The most recent time the U.S. involved the Defense Production Act was in 2022, in order to enhance U.S. manufacturing of large storage batteries.

> "On March 31, 2022, the president signed a determination permitting the use of Defense Production Act (DPA) Title III authorities to strengthen the U.S. industrial base for large-capacity batteries. With this action, the president gave the Department of Defense (DoD) the authority to increase domestic mining and processing of critical materials for the large-capacity battery supply chain." Press Release, Defense Production Act Title III Presidential Determination for Critical Materials in Large-Capacity Batteries, US Department of Defense, April 5, 2022,

ANNEX: Examples of US competition cases that mandate transfer of technology and know-how

The Ciba-Geigy case requires access to patented inventions, technical information and know-how, and the possibility of a trustee to manage the transfer if necessary.

[Federal Register: January 3, 1997 (Volume 62, Number 2)]
[Notices] [Page 409-414]

https://www.federalregister.gov/documents/1997/01/03/97-5/ciba-geigy-limited-et-al-analysis-to-aid-public-comment

FEDERAL TRADE COMMISSION
[File No. 961-0055]

Ciba-Geigy Limited, et al.; Analysis to Aid Public Comment
AGENCY: Federal Trade Commission.
ACTION: Proposed Consent Agreement.
. . . .
By September 1, 1997, Sandoz and Chiron each are required to grant a non-exclusive license to Rhone-Poulenc Rorer (``RPR''), with whom Ciba, Sandoz and Chiron have entered into a letter of intent for this purpose. If the agreement between RPR and Ciba, Sandoz, and Chiron were to fall through, Ciba, Sandoz and Chiron would be required to license these assets to another licensee who has received Commission approval by September 1, 1997. Under the terms of the proposed Order, the license granted to RPR, or an alternative licensee, must include the right to sublicense in fields that are not developed by RPR or the licensee, as well as a technology transfer from Sandoz of necessary HSV-tk know-how, including know-how relating to vectors, within one year of execution of the license.

Third, to ensure the continued research, development, manufacture and sale of Factor VIII gene therapy products for the treatment of hemophilia A, the proposed Order requires that by September 1, 1997, Sandoz shall either: (1) convert its exclusive license for the use in gene therapy of the partial Factor VIII gene to a non-exclusive license; or (2) grant to RPR a sublicense to those gene therapy Factor VIII rights. At the option of the sublicensee, Sandoz may be required to provide technical information and know-how relating to Factor VIII gene therapy products.

Finally, to ensure the continued research, development, manufacture and sale of chemoresistance gene therapy products in the United States, the proposed Order requires that neither Ciba, Chiron, Sandoz nor Novartis shall acquire exclusive rights in intellectual property and technology related to the MDR-1 and/or MRP genes. With exclusive rights to the genes necessary for this treatment area, both parties would have potentially dominating intellectual property rights for the use of the MDR-1 or MRP chemoresistance genes in gene therapy. The merger combines the parties' two competing chemoresistance gene therapy programs and potentially concentrates the important intellectual property rights for these genes. Thus, the proposed restriction on exclusive licensing of the MDR-1 and MRP genes will ensure access to the chemoresistance genes to at least one other competing company.

The proposed Order also provides for the appointment of a trustee if Novartis and/or Chiron fail to grant any of these licenses within the appropriate time period. In that event, the trustee is authorized to divest either Sandoz' or Chiron's HSV-tk businesses in their entirety.
. . .

Quaker Chemical Corporation and Global Houghton Ltd.; Analysis of Agreement Containing Consent Orders To Aid Public Comment

https://www.federalregister.gov/documents/2019/07/30/2019-16152/quaker-chemical-corporation-and-global-houghton-ltd-analysis-of-agreement-containing-consent-orders

Quaker Chemical Corporation and Global Houghton Ltd.; Analysis of Agreement Containing Consent Orders To Aid Public Comment
84 FR 36923
A Notice by the Federal Trade Commission on 07/30/2019

To remedy harm in the market for AHRO, Quaker will divest to Total: (1) Houghton's formulations, intellectual property, including patent for non-oleic acid formula, trade secrets, including know-how for its AHRO; (2) customer contracts for North America; (3) key Houghton employees that are responsible for the commercial and technical aspects of the AHRO business; and (4) adjacent products including fire resistant hydraulic fluids.

To remedy harm in the market for SCRO, which includes sheet cold rolling oil, TPRO, and pickle oil, Quaker will divest to Total: (1) Houghton's formulations, trade secrets and intellectual property, including know-how for sheet cold rolling oils, TPRO, and pickle oil; (2) customer contracts for North America; (3) key Houghton employees that are responsible for the commercial and technical aspects of the SCRO business; and (4) SCRO and TPRO cleaners.

Baxter International, Inc., and Wyeth Corporation; Analysis To Aid Public Comment

https://www.federalregister.gov/documents/2003/01/08/03-309/baxter-international-inc-and-wyeth-corporation-analysis-to-aid-public-comment

Baxter International, Inc., and Wyeth Corporation; Analysis To Aid Public Comment
A Notice by the Federal Trade Commission on 01/08/2003

The Consent Agreement also requires the parties to license certain additional know-how that relates, but does not exclusively relate, to propofol to the propofol acquirer. . . .

Pursuant to the terms of the Order, the Commission has appointed William E. Hall as a Monitor Trustee to ensure Baxter's and Wyeth's compliance with all of the requirements of the Order. Mr. Hall has over 30 years of experience in the pharmaceutical industry and is well-respected in the industry. In order to ensure that the Commission remains informed about the status of the proposed

divestitures and the transfers of assets, the Consent Agreement requires Baxter and Wyeth to file reports with the Commission periodically until the divestitures are accomplished.

Dainippon Ink and Chemicals, Incorporated; Analysis To Aid Public Comment

https://www.federalregister.gov/documents/2003/02/25/03-4396/dainippon-ink-and-chemicals-incorporated-analysis-to-aid-public-comment
Dainippon Ink and Chemicals, Incorporated; Analysis To Aid Public Comment
A Notice by the Federal Trade Commission on 02/25/2003

Ciba will receive all of the assets it needs to replace the competition offered by Sun Chemical in the perylene market before the Proposed Acquisition. Under the Consent Agreement, Sun Chemical will divest its entire perylene business to Ciba. The divestiture includes: All of Sun Chemical's current perylene products; all perylene research and development; manufacturing technology; scientific know-how; technical assistance and expertise; customer lists; raw material, intermediate, and finished product inventory; and perylene product names, codes, and trade dress. Because Sun Chemical manufactures perylenes through toll manufacturers, no manufacturing equipment or facilities are included in the divestiture. Instead, as required by the Consent Agreement, Ciba has entered into contracts with Sun Chemical's perylene toll manufacturers—Lobeco Products and Forth Technologies—that will become effective upon closing the divestiture.

Additionally, the Consent Agreement includes several measures to ensure an effective transition of the tangible and intangible assets related to the perylene business from Sun Chemical to Ciba. First, Ciba will have the opportunity to hire one or more Sun Chemical employees who have key responsibilities in connection with the company's perylene business. These former Sun Chemical employees will help Ciba not only to understand Sun Chemical's perylene manufacturing, research, and development process, but also to identify any missing or incomplete assets in the divestiture. Second, the Consent Agreement requires Sun Chemical to provide technical assistance to Ciba for a period of one year following the divestiture to help Ciba successfully take over Sun Chemical's perylene product line. Third, under the Consent Agreement, the Commission may appoint an interim monitor to supervise the transfer of assets and assure that Sun Chemical provides adequate technical assistance to Ciba.

Finally, in the event that the divestiture of Sun Chemical's perylene business to Ciba fails, the Consent Agreement includes certain contingent provisions to remedy the Proposed Acquisition's anticompetitive effects. If, before the Commission finalizes the Consent Order in this matter, the Commission notifies Dainippon that Ciba is not an acceptable acquirer of Sun Chemical's perylene business or that the manner in which the divestiture to Ciba was accomplished was not acceptable, the Consent Agreement requires Dainippon to rescind the transaction with Ciba and divest Sun Chemical's perylene business to an acquirer that receives the prior approval of the Commission within ninety (90) days of the rescission. Additionally, if Dainippon does not divest Sun Chemical's perylene business to either Ciba or a Commission-approved acquirer within the time required by the

Consent Agreement, the Commission may appoint a trustee to divest Sun Chemical's perylene business in a manner that satisfies the requirements of the Consent Agreement.

Cephalon, Inc., et al.; Analysis To Aid Public Comment

https://www.federalregister.gov/documents/2004/08/25/04-19443/cephalon-inc-et-al-analysis-to-aid-public-comment
Cephalon, Inc., et al.; Analysis To Aid Public Comment
A Notice by the Federal Trade Commission on 08/25/2004

The proposed Consent Agreement therefore requires Cephalon to grant a license and transfer all of its technological know-how and intellectual property related to Actiq ("Actiq license assets") to an upfront buyer no later than ten days after the acquisition is consummated. Cephalon has selected Barr Laboratories, Inc. ("Barr") as the upfront buyer. Barr is a reputable generic manufacturer and is well-positioned to manufacture a generic version of Actiq. If the Commission determines that Barr is not an acceptable purchaser, or if the manner of the grant, license, delivery or conveyance is not acceptable, Cephalon and Cima must rescind the transaction with Barr and grant, license, deliver or otherwise convey the Actiq license assets to a Commission-approved buyer not later than six months from the date the Order becomes final. Should they fail to do so, the Commission may appoint a trustee to divest the Actiq license assets.
. . . .
With the licenses and technology transfer provided by Cephalon, Barr will be able to compete aggressively in the BTCP market against Actiq. The proposed remedy also prohibits Cephalon from making certain regulatory filings that would delay FDA approval of Barr's generic Actiq. These provisions ensure that Barr will be in a position to launch a generic version of Actiq no later than OVF launch, eliminating the anticompetitive effects of the proposed acquisition and providing patients with earlier access to a lower priced generic product.

Owens Corning; Analysis of Agreement Containing Consent Order to Aid Public Comment

https://www.federalregister.gov/documents/2007/11/01/E7-21509/owens-corning-analysis-of-agreement-containing-consent-order-to-aid-public-comment

Owens Corning; Analysis of Agreement Containing Consent Order to Aid Public Comment
A Notice by the Federal Trade Commission on 11/01/2007

The purpose of the divestiture and licensing is to give AGY all assets and know-how necessary for the production and sale CFM products.
. . .

The proposed Decision and Order also allows for the parties to enter into transition agreements for the short term provision of services, including an agreement for the supply of the raw materials for the production of Marbles. . ..