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**Joint briefing paper**

## **European Directive on trade secrets: A threat to access to public health data**

In late November 2013, the European Commission released its proposed directive on the “*protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure*” (1).

This proposal is strongly supported by multinationals and corporate lawyers (2). Its extremely broad and vague scope makes it impossible to fully assess the consequences it would have in practice, in particular in terms of freedom of information and expression for European citizens or on competition (see inset on page 6). On the other hand, it provides for very severe penalties that would endanger the work of individuals or organisations lacking the resources to defend themselves effectively in the event of abusive litigation: investigative journalists, whistle-blowers and small and medium-sized companies (2,3). It is precisely for these reasons that in France, in late January 2015, the government eventually withdrew several controversial amendments concerning trade secret protection from a draft law (a).

In its position adopted in May 2014, the Council of Ministers does not seem to have understood the full extent of the dangers posed by the European Commission’s proposed directive. It even encouraged Member States to adopt additional measures to protect trade secrets on top of those provided by the proposed directive (4). As of early 2015, it is now the turn of the European Parliament to discuss the proposed directive.

**The wrong target?** Recent revelations concerning industrial espionage conducted by the United States’ National Security Agency (NSA), in particular via computer networks, show that the protection of the competitiveness of European businesses depends in large part on their ability to protect their IT system (5,6). However, the proposed directive on “trade secrets” does not address this subject at all. It is using the argument of defending European businesses to align European law with US law (see inset on page 6). But, in practice, this would restrict European citizens’ freedom of information, including information about public policies affecting public health (3).

**Anti-transparency effort.** The proposed directive on trade secrets was published in late November 2013, at a time when, during adoption of a new European regulation on clinical trials, Member State health ministers and MEPs supported greater transparency concerning clinical data, while pharmaceutical companies wanted these data to be considered “*commercially confidential*” (b,c) (7,8).

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**a-** In France, in early January 2015, amendments concerning trade secret protection had been incorporated into a bill for economic growth and activity and equal opportunities (the Macron Act). The notion of “trade secret protection” had been included in French Commercial Code and stated that anyone violating trade secrets would be liable to three years imprisonment and a €375 000 fine (refs 14,15). The French government withdrew these amendments on 29 January 2015 in the face of general outcry (ref 16).

**b-** In particular, health ministers supported the European Medicines Agency’s decision to publish clinical study reports, documents that present the results of trials in a detailed manner. They underlined that clinical data “*should not be considered commercially confidential (...)*”. Public access to clinical data is essential to enable independent review of trial results, to ensure that reliable information is available on the efficacy and adverse effects of medicines (refs 7,17).

**c-** On the very day the proposed trade secrets directive was published, the European Federation of Pharmaceutical Industries and Associations (EFPIA) welcomed it, stating: “*Almost every aspect of the drug development process involves the generation and application of substantial amounts of technical information and know-how, including the preclinical chemistry, manufacturing and control process as well as clinical trials phase*” (ref 18).

Pharmaceutical companies and other multinationals then pushed for trade secret protection to be considered a priority during negotiations for the trade agreement between the United States and the European Union (d) (9).

**Greater protection of intellectual property?** In the European Union, trade secrets are not covered by intellectual property rights because they do not form part of a social contract, unlike patents, where society grants a temporary monopoly in exchange for publication of the invention (e).

The European Commission claims in its proposal that enhanced protection of trade secrets is likely to “improve the conditions/framework for the development and exploitation of innovation (...)” (1). Yet, the proposal’s impact assessment notes that 60% of European Union companies already share their trade secrets through collaborations, using when necessary non-disclosure agreements and contracts (10). Clearly, in reality knowledge transfer and information exchange are more crucial to research and innovation than the protection of trade secrets(f).

In reality, this directive would impose stricter standards on trade secrets, similar to intellectual property protection, on EU Member States, paving the way for the inclusion of trade secret protection in the Transatlantic Trade and Investment Partnership (TTIP), currently under negotiation. This agreement will then serve as a basis for negotiation with other member countries of the World Trade Organization (g).

**A very broad definition of “trade secrets”, including scientific data that is in the public interest.** The definition of trade secrets proposed by the European Commission includes all non-public information with economic value, therefore any document or information that would harm the reputation of the company concerned if published by a journalist, whistle-blower or researcher (Article 2(1)) (h).

It is particularly worrisome that this definition does not allow for the exclusion of scientific data that is in the public interest, such as regulatory data (i). In fact, in early 2015, the MEP in charge of drafting the opinion of the European Parliament’s Committee on the Internal Market and Consumer Protection suggested adding to this definition: “concerns trials, tests or other secret data which, in order to be developed, require a significant commitment and upon the submission of which marketing authorisation for chemical, pharmaceutical or agricultural products involving the use of new chemicals depends” (11).

In 2013 and 2014, pharmaceutical and food processing companies had already lodged complaints against the European Medicines Agency (EMA) and the European Food Safety Authority (EFSA) in order to

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**d-** In early 2014, the pharmaceutical industry’s wish-list during negotiation of the trade agreement between the European Union and the United States was leaked to civil society and included : “(...) agree on which [clinical trial result data fields] may be disclosed to public (uniform protection of confidential commercial info and trade secrets)” (ref 9). The association that represents the United States’ pharmaceutical industry (PhRMA) also explicitly asked its government to use the Transatlantic Trade and Investment Partnership (TTIP) negotiations to block the European Medicines Agency’s plans to publish clinical study reports (ref 19).

**e-** Patents are granted in return for publication of the innovation. These rights give exclusive use of the invention to the company or person that filed the patent application (the right holder). In practice, no other company or person is allowed to use, manufacture or import the innovation without the right holder’s consent for 20 years from the filing date (ref 20). The situation for trade secrets is different: “trade secrets holders” do not make their work public and therefore do not participate in disseminating the innovation.

**f-** This is why the state of California, host to Silicon Valley and its IT giants, prohibits clauses in employment contracts that could prevent employee mobility (ref 21).

**g-** Given that the Trade Related Intellectual Property Rights (TRIPS) agreement, adopted in 1994, hindered access to generic drugs in developing countries, extreme vigilance is required (ref 22).

**h-** Trade secrets are defined in Article 2(1) of the proposed directive as:

“information which meets all of the following requirements:

a) is secret (...);

b) has commercial value because it is secret;

c) has been subject (...) to reasonable steps (...) to keep it secret”.

**i-** The definition proposed by the European Commission is in reality broader than the “undisclosed information” of the World Trade Organization’s 1994 agreement on Trade Related Intellectual Property Rights (TRIPS agreement - Article 39). In the TRIPS agreement, regulatory data (results of clinical trials included in marketing authorisation applications for new drugs, results of toxicology studies on new chemical products, etc.) are not considered “undisclosed information”, because they are not of a commercial nature (ref 23). In addition, their acquisition is only punishable if they are disclosed or used “in a manner contrary to honest commercial practices”, rather than simply without the consent of the trade secret “holder” (ref 24).

prevent the disclosure of data they considered “*commercially confidential*” (3,12). Is it wise to offer companies wider means to oppose transparency of scientific data?

**A repressive approach.** While secrets do not form part of the same social contract as patents, the proposed directive provides for an arsenal of penalties to be applied by Member States, similar to the penalties for breaching a patent, including precautionary measures (seizure or destruction of products suspected of having been produced using an unlawfully acquired trade secret), payment of damages, etc. (Articles 9,11,13). These penalties would also apply to third persons who “*should, under the circumstances, have known that the trade secret was obtained from another person who was using or disclosing the trade secret unlawfully*” (j).

The Council also increased the period during which the “legitimate trade secret holder” would be allowed to bring legal action from 2 to 6 years “*after the date on which the applicant became aware, or had reason to become aware, of the last fact giving rise to the action*” (k) (Article 7).

**Restrictions on the freedom of expression of journalists and whistle-blowers.** The fact that “*legitimate use of the right to freedom of expression and information*” was one of the few exceptions in which the “*measures, procedures and remedies*” provided for in the directive could not be applied is insufficient (Article 4(2)) (l). For example, the directive states that whistle-blowers can only use undisclosed information for the purpose of revealing “*misconduct, wrongdoing or illegal activity*” and only “*provided that the alleged acquisition, use or disclosure of the trade secret was necessary for such revelation and that the respondent acted in the public interest*” (m). Such a provision acts as a deterrent and prevents efforts to access and disclose information.

**In summary: dubious benefits, but a genuinely retrograde step for society at large and individual liberties.** The implementation of such a proposal would threaten the fundamental individual liberties of European citizens, in particular journalists and whistle-blowers. In addition, by shifting documents that are currently in the public domain to the trade secrets domain, this directive would constitute a major retrograde step for the right of citizens to access information that is in the public interest and affects them.

Like many non-governmental organisations, **we oppose the attempt to hastily push this proposed directive through** to enable the inclusion of trade secret protection in the TTIP, currently under negotiation (3). A sensitive subject such as this requires real democratic debate and broad public consultation, in which opposing views are represented and discussed, particularly those of journalists and non-governmental organisations.

**If this proposed directive were to be adopted, it would require major amendments**, in particular in order to (13):

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j- The proposed directive would have safeguarded the confidentiality of trade secrets during legal proceedings to such an extent that the parties would be denied a fair trial, prompting the European Council to amend these provisions. In accordance with Article 47 of the Charter of Fundamental Rights of the European Union, the Council insisted that “*at least one person from each party, its respective lawyer or representative*” must be given access to all of the evidence and documents (ref 4, Article 8 and ref 25).

k- The European Commission had proposed a limit of 2 years, a period more compatible with employment rights, in particular those of employees who participated in the development of new techniques or products and could be sued by their former employers, so as not to impede worker mobility (ref 1).

l- The notion of “legitimate interest” is open to interpretation. In addition, in its position adopted in May 2014, the Council removed the stipulation that the unauthorised disclosure or use of a trade secret would only be unlawful if carried out intentionally or with gross negligence, yet the purpose of this stipulation was to prevent abusive litigation (ref 4, Article 3).

m- Yet it is often only possible to assess whether disclosure was necessary with hindsight. And it is not easy to determine which information could be considered to demonstrate “misconduct” or “wrongdoing”. What would the situation be for example if someone were to reveal that a particular company was planning mass redundancies? Or serious suspicions that a pharmaceutical company may have concealed the adverse effects of a particular drug, which could only be confirmed by an enquiry?

- exclude from the definition of “trade secret” information whose disclosure is in the public interest or could be considered a matter of fundamental rights; and information whose publication is required by European or national regulations or that is a responsibility of public authorities (*Article 2*);
- explicitly include information of this nature as exceptions, to which the “*measures, procedures and remedies*” provided for by the directive would not apply (*Article 4(2)*);
- ensure that implementation of the directive does not enable new exclusive intellectual property rights to be granted for trade secrets, since there is no return for society, such as public disclosure of an invention (replace certain terms that are much closer to intellectual property law (*Article 2*));
- add a clear reference to the effect that the directive must not prevent the European regulation on freedom of information and access to documents (Regulation (EC) No. 1049/2001), as well as national freedom of information laws, needs to be respected (*adopt Recital 10a proposed by the Council*);
- maintain the precautions provided by the European Commission to prevent abusive litigation; and add a clear statement that the onus is on the applicant (i.e. the trade secret “holder” who instigated legal proceedings) to prove that the “trade secret” was acquired or used unlawfully, as well as to demonstrate that the publication of the “trade secret” does not qualify as an one of the exceptions, to which the measures provided for by the directive would not apply (*Article 6*).

**Corporate Europe Observatory**  
**International Society of Drug Bulletins**  
**Medicines in Europe Forum**

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### Endorsing Organisations

**Corporate Europe Observatory (CEO)** is a research and advocacy organisation that conducts campaigns about the threats posed by the economic and political power of major companies and their [lobbies](#) to democracy, equity, social justice and the environment. For more information: <http://corporateeurope.org>; Contact: [martin@corporateeurope.org](mailto:martin@corporateeurope.org)

**ISDB.** The International Society of Drug Bulletins (ISDB), founded in 1986, is a worldwide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently ISDB has around 80 members in 41 countries around the world. More info: [www.isdbweb.org](http://www.isdbweb.org); Contact: [press@isdbweb.org](mailto:press@isdbweb.org)

**MiEF.** The Medicines in Europe Forum (MiEF), launched in March 2002 with about 60 member organizations, represents the four key players on the health field, i.e. patients groups, family and consumer bodies, social security systems, and health professionals. It is a testament of the importance of European medicines policy. Admittedly, medicines are no mere consumer goods, and the Union represents an opportunity for European citizens to seek further guarantees of efficacy, safety and pricing. Contact: [pierrechirac@aol.com](mailto:pierrechirac@aol.com)

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## Protection of trade secrets: pressure from multinationals on both sides of the Atlantic

Greater protection for trade secrets is a recurrent demand from multinationals, within a broader context in which intellectual property rights have been increasing constantly worldwide since the end of World War II (a,b) (1). The issue for these companies is to preserve their partial monopoly for as long as possible (2).

**Industry lobbying on both sides of the Atlantic.** In the European Union, the European Commission's proposed directive on trade secrets is strongly supported by an organisation called the "Trade Secrets & Innovation Coalition", which includes Alstom, DuPont de Nemours, General Electric, Intel, Michelin, Air Liquide, Nestlé and Safran, companies that work with the food, pharmaceutical and chemical industries (3,4).

In the United States, two new bills published in 2014 are currently being considered in the House of Representatives and the Senate: the Trade Secrets Protection Act and the Defend Trade Secrets Act (5-7).

**The United States in the driving seat.** The strategy of the United States government to minimise threats to US trade secrets, released in February 2013, states: "*The United States urges its trading partners to ensure they have robust systems for protecting trade secrets, including deterrent penalties for criminal trade secret theft. USTR [the Office of the United States Trade Representative] will monitor developments in this area*" (8).

A United States news website summarised what is at stake in the proposed European directive on trade secrets as follows: "*[the directive] would harmonize the definition and treatment of trade secrets across European Union member states [and] would bring it largely in line with the civil enforcement approach taken in the United States (...)*" (9).

In July 2014, the European Commission confirmed that "*In recent Free Trade Agreement*

*negotiations requests have often been made, for example, to include the protection of trade secrets*" (10, Section 3.3.1 "Building on EU legislation").

**First in their sight: the Transatlantic Trade and Investment Partnership (TTIP).** In the United States and the European Union, the adoption of these texts would pave the way for the inclusion of trade secret protection in the Transatlantic Trade and Investment Partnership (TTIP) agreement, currently under negotiation behind closed doors, and which will be virtually impossible to repeal in the future through democratic processes (11,12).

The TTIP trade agreement will also serve as a basis for negotiating stronger intellectual property rights with other member countries of the World Trade Organization. The Trade Related Intellectual Property Rights (TRIPS) agreement adopted in 1994, which, despite various adjustments to make it more "flexible", hinders access to generic drugs in developing countries, should prompt caution (13,14).

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a- A number of agreements were formulated and signed after World War II, with the intention of promoting peace by facilitating trade between the various nations. These GATT (General Agreement on Tariffs and Trade) agreements focused mainly on the liberalisation of the trade of goods. They eventually led to the creation of the World Trade Organization (WTO) in 1994.

b- At the request of wealthy countries, including their pharmaceutical companies which were unhappy about lost sales due to competition from emerging countries that were producing copies and generic drugs (e.g. India and Brazil), intellectual property rights were added to the agenda of WTO trade agreement negotiations (ref 1). In 1994, an agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was annexed to the WTO agreement. Among other things, the TRIPS agreement requires countries to respect patents (refs 1,15).

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