Decision in case 1606/2016/JAS on the European Medicines Agency's handling of an alleged failure to declare interests by its Executive Director

Decision
Case 1606/2016/JAS - **Opened on** 05/12/2016 - **Decision on** 22/11/2017 - **Institution concerned** European Medicines Agency (No maladministration found) |

In October 2016, a complaint was made to the European Ombudsman alleging that the Executive Director of the European Medicines Agency (EMA) had not declared all his relevant interests to EMA. The complainants contended that this failure to declare certain interests was in breach of EMA's own rules requiring the declaration of all relevant interests by staff and that EMA had failed to deal with this situation appropriately.

EMA's Executive Director had, prior to joining EMA in 2011, worked for an Italian public research body. In that context, he had, in cooperation with a number of other researchers, conducted research in the field of pharmaceutics. Some of that research gave rise to inventions for which patent applications were made (some of these later resulted in patents being awarded). The complainants believed that the Executive Director had wrongly failed to inform EMA of these patents.

The Ombudsman inquired into the issue. She found that the Executive Director was indeed one of the co-inventors named in the patent applications. However, she also established that the Executive Director did not own any of the intellectual property rights relating to those inventions when he joined EMA. This was because, for some of the inventions, he had never held any intellectual property rights. For one other invention, he had transferred his share of the rights to the pending patent application to the other co-inventors, free of charge, before joining EMA. The Ombudsman also found that the Executive Director had not financially benefitted from, or retained any other financial interests in, any of the patents or patent applications.

The Ombudsman thus concluded that the Executive Director had not failed to declare any relevant interests when he joined EMA in 2011 and that there was no maladministration by EMA in its obligation to ensure that the Executive Director had declared all relevant interests.

However, the Ombudsman suggests ways for EMA to further strengthen its rules on declarations of interests by its staff.

Background to the complaint

1. The complaint, made by three researchers, a medical doctor, and a Member of the European Parliament, concerns the European Medical Agency's (EMA) handling of allegedly undeclared interests of its Executive Director.

2. In May 2016, the complainants contacted EMA stating that it appeared to them that the Executive Director had not declared that he was the inventor of several patents in the field of pharmaceutics.

3. EMA replied that the Executive Director had not been obliged to declare the patents.

4. The complainants submitted a complaint to the Ombudsman in October 2016.

The inquiry

5. The Ombudsman opened an inquiry into the complaint. The complainants' position is that EMA failed to ensure that the Executive Director declared all relevant interests in his publicly available declaration of interests.

6. The Ombudsman first met with EMA to clarify the facts. The Ombudsman then wrote to EMA asking it to reply to a number of detailed questions. These questions were based on the documentation provided to her by the complainants and on public records of patents and patent applications. After examining EMA's reply, the Ombudsman asked EMA for additional information and clarifications on a number of remaining issues. The Ombudsman's decision takes into account the arguments put forward by the complainants as well as the information and documentation obtained during the Ombudsman's detailed inquiry into the complaint.

The allegedly undeclared interests

Arguments presented to the Ombudsman

7. The complainants identified five patent families (sets of patents registered in various countries to protect a single invention) which, according to public records, were linked to the Executive Director. The complainants argued that the Executive Director should have declared these patents to EMA (the Executive Director's declaration of interests does not mention any patents).

8. EMA stated that the Executive Director was one of the *inventors* of the claims outlined in these patents. He did not, however, *own* any of the patents. EMA stated that its own rules [1] in this area did not oblige its staff to declare any patents for which a staff member was the

inventor, but not the owner (unless they were entitled to financial benefits as the inventor). Regarding the Executive Director, EMA said he never had any financial interest or benefit arising from any of the patents.

The Ombudsman's assessment

EMA's rules on conflicts of interest

9. EMA's staff are subject to the rules and regulations applicable to European Union officials and other staff [2] , which include the rights and obligations outlined in the EU's Staff Regulations [3] . These provide that the principal duty of any EU civil servant is to conduct himself or herself solely with the interests of the Union in mind [4] . That means that, as a general rule, an EU civil servant should not, in the performance of his or her duties, deal with a matter in which, directly or indirectly, he or she has any personal interest such has to impair his or her independence. This applies in particular to financial interests [5] .

10. EMA has put in place its own rules implementing these general principles [6] . These rules provide that, when they take up employment at EMA, staff are required to submit **declarations listing their relevant interests** [7] . EMA staff are required to update these declarations annually. The declarations are assessed by EMA and staff are assigned one of the three 'interest levels' specified in the rules [8] . The declarations of EMA management staff are available on its website [9] . EMA makes other declarations available upon request [10] .

11. EMA distinguishes between interests which are 'allowed' and those which are 'not allowed', as well as between 'direct' and 'indirect' interests [11] . Interests that are considered to be not allowed are those which are incompatible with a staff member's involvement in **any** activity of EMA. Interests that are considered to be 'allowed' are not considered to be incompatible with all of EMA's activities. However, the staff member might be subject to certain restrictions and mitigating measures depending on the nature of his or her duties at EMA and the nature of the interest declared. **Direct interests** are interests of personal benefit to the individual (for example, employment or financial interests), and **indirect interests** are other interests that may have some influence over the individual's behaviour (for example, previous research work for a pharmaceutical company).

12. At the time when the Executive Director joined EMA, EMA's declaration of interest rules [12] required EMA staff to declare any ownership of patents for a "medicinal product/competitor product". The rules did not allow staff to own such patents while working at EMA. Patents owned within the period of five years before the start of employment at EMA, but disposed of prior to joining EMA, also had to be declared. The rules did not require staff to include in their declarations any patents for which they were merely the *inventor* , unless they somehow benefited financially from the invention.

13. The Ombudsman will assess the issue complained about in light of the rules set out above. In her conclusion, the Ombudsman will also comment on EMA's current rules on the handling of

declared interests, which entered into force on 1 January 2017 [13] .

Inventor, applicant and owner of a patent

14. It is important to distinguish between 1) the inventor of something for which a patent may be sought, 2) the person applying for a patent and 3) the owner of a patent, as the rights that flow from these roles differ.

15. The **inventor** is the creator of an invention which can give rise to a patent. “Inventors” are always people (and not, for example, the companies for which these people work). Inventors are legally entitled to be designated on the patent documentation as being the “inventor”, regardless of who files the patent application or who owns the eventual patent. Joint inventors or *co-inventors* exist when a patentable invention is the result of the inventive work of more than one inventor [14] .

16. The **patent applicant** is the person or entity submitting the patent application to the responsible patent authorities. The patent applicant need not necessarily be the inventor. This would occur in cases where the rights to the invention have been contractually assigned to another entity before the application is made. The inventor, however, will always keep the right to be *mentioned* as the inventor in the application. For example, it is frequently the case that, in the context of an employment relationship, rights to inventions created by employees are (pre-)assigned to the employer by the employment contract [15] or considered as belonging to the employer by law [16] . In that case, the applicant (and future owner of the patent) is not the “inventor”.

17. The **patent owner** is the owner of the exclusive rights flowing from a patent, such as the exclusive right to exploit the invention financially, for example by marketing the invention or licencing it to a third party.

18. EMA’s rules focus on declaring patent ownership only.

Patent applications submitted by a US pharmaceutical company

19. Public records show that EMA’s Executive Director is named as co-inventor on two international patent applications [17] made in 2002 and 2003. The patent applicant for these inventions is a US pharmaceutical company.

20. EMA stated that the inventions referred to in these patent applications were the result of research funded by that pharmaceutical company and performed by a public research body in Italy. The contracts entered into by the pharmaceutical company and the public research body to fund the research stated that the pharmaceutical company acquired any and all rights to inventions that might arise from that research. At that time (from 1990 to 2008), EMA’s Executive Director was an employee of that research body. In accordance with Italian law, he and the other researchers who worked on the inventions were entitled to be named, in the patent applications, as co-inventors. However, they acquired no ownership rights over the

inventions.

21. EMA provided the Ombudsman with a statement made by the pharmaceutical company concerned to this effect. The company stated that the Executive Director *"holds no economic interests in these patents. He has not received and will not receive from* [the company] *any payment with respect to these patents"* .

22. Concerning one of the inventions, all patents or patent applications have now expired or were abandoned (the European patent application was withdrawn). Concerning the other invention, a number of patents were granted to the US pharmaceutical company.

23. The Ombudsman thus concludes that the Executive Director neither applied for any patents nor did he own any patents based on these inventions . The available information also supports EMA's statement that he has not received any remuneration from the US pharmaceutical company for the inventions. Finally, since the patent applications were made in 2002 and 2003, the relevant research must have taken place many years before the Executive Director started his employment at EMA in 2011.

24. By way of completeness, EMA has stated that the active ingredient that was the subject of the research in question is not contained in any medicinal product for which EMA has conducted any scientific assessment. In particular, the pharmaceutical company has never submitted to EMA a marketing authorisation application for a product based on this ingredient.

Patent applications submitted by an Italian pharmaceutical company

25. Public records show that the Executive Director is named as co-inventor on two more international patent applications [18] , both made in 2006. The patent applicant for these inventions is an Italian pharmaceutical company.

26. EMA stated that the Italian pharmaceutical company had not itself been involved in the research leading to the two patent applications. Rather, it acquired the rights after the research had been completed. The inventions claimed in these patent applications were the result of research conducted by the public research body mentioned in paragraph 20 and an Italian university. The university had agreed that all resulting inventions would be owned by the researchers themselves, who in turn committed to maintaining (that is, paying for) and prosecuting the patent applications. Thus, the initial patent applicants were three of the researchers. Regarding the Executive Director of EMA, who was one of the co-inventors, he had assigned *free of charge* all of his rights to the inventions to the three other co-inventors before the patent applications were submitted in 2006. EMA provided the Ombudsman with affidavits from the three co-applicants confirming this. The public record shows that the Executive Director was mentioned on the patent applications as a co-inventor, but not as a co-applicant.

27. In 2007, the pharmaceutical company acquired all rights to these inventions from the three co-applicants. Since the Executive Director had already transferred his rights to the other

researchers before the patent applications were even made, he was not part of the contract concluded between the co-applicants and the Italian pharmaceutical company, and received no remuneration from the company.

28. As of 2012, both patent applications were deemed to be withdrawn, which means that no patents were granted on the basis of the applications.

29. The Ombudsman thus concludes that the Executive Director neither applied for a patent nor did he own any patent based on these inventions . According to the available evidence, he did not receive any remuneration from the Italian pharmaceutical company for the inventions.

30. EMA has also stated that the active ingredient which was the subject of the research is not contained in any medicinal product for which EMA has conducted a scientific assessment. The Italian pharmaceutical company has never submitted to EMA a marketing authorisation application for a product based on this ingredient.

Patent application submitted by a group of researchers

31. The Executive Director is also named as co-inventor and one of five co-applicants on a patent application filed in 2004. Based on this application, a number of identical patents in different countries were issued, including a European patent, which was granted in mid-2012 to the co-applicants (who are now the patent co-owners). In late 2012, the European Patent Office recorded a free of charge transfer of the Executive Director's share of the patent ownership to the other patent co-owners. The Ombudsman considered it necessary to seek clarifications from EMA on this point.

32. According to EMA, the transfer of rights in question had in fact already taken place in March 2010, that is, before the patent had been granted and before the Executive Director started his employment at EMA in 2011. In support of this, EMA provided the Ombudsman with a statement by the patent agent involved, as well as with affidavits signed by the other researchers. Furthermore, the patent agent stated that the Executive Director was billed for the patent application maintenance fees only until March 2010, after which it was the other researchers who paid for the maintenance of the application. According to EMA, the Executive Director said that he was, in 2010, no longer willing to invest money in the maintenance of the application (as he doubted that the invention would ever give rise to a medicinal product). The patent agent also explained that the other researchers then waited two years before filing the documentation relating to the transfer of rights with the European Patent Office. The reason they waited was because they wished to avoid paying certain fees. Once the Patent Office granted the patent in mid-2012, the researchers submitted **the pre-existing transfer documents** . That is the reason, EMA stated, why the Patent Office did not register the transfer of the rights until 2012.

33. The Ombudsman thus concludes that the Executive Director never (co-) owned a patent based on this patent application . He was a patent applicant until 2010, but was not a

patent applicant when he joined EMA in 2011. According to the available evidence, he did not receive any remuneration from the other researchers for his share of the invention (the transfer in 2010 was free of charge).

34. Finally, EMA stated that no medicinal product was developed based on the invention claimed in this patent. According to the public record, the patent is still owned by the four other researchers.

Conclusion on the five patent applications

35. It is reasonable for EMA to require staff to declare patents they own while working for EMA. Such patents can be financially exploited by their owners and can potentially conflict with their work for EMA (for example, if EMA were called upon to authorise a medicine based on the patents). Likewise, staff members should also declare any other financial benefits they may have which are linked to patents (such as any *contractual* rights to benefit from the future exploitation of a patent).

36. The Ombudsman's inquiry has established that the Executive Director did not own any patents based on the five patent applications brought to the Ombudsman's attention by the complainants. Evidence obtained by the Ombudsman during the inquiry also shows that the Executive Director did not receive any financial compensation for any of the patent applications.

37. Furthermore, a search of publicly available databases has not revealed any additional international patents or patent applications linked to the Executive Director.

Since the Executive Director neither owned, nor financially profited from, any patents the Ombudsman concludes that the Executive Director did not fail to declare any relevant interests when he joined EMA. The applicable rules did not require the Executive Director to declare that he was one of the *inventors* named in the applications. This is reasonable since, being an inventor does not, in itself, give rise to any financial interests that could have affected his work at EMA. Arising from this conclusion, the Ombudsman finds that there was no maladministration by EMA in its obligation to ensure that its Executive Director declared all of his relevant interests.

EMA's current rules on declaring interests

38. In the course of the inquiry the Ombudsman learned that EMA has recently changed its rules relating to declarations of interests. EMA's *current* rules [19] state that the ownership of patents needs to be declared by staff only if there is a link between the patent and a *pharmaceutical company* . The previous rules required the declaration of any ownership of a patent for a "medicinal product/competitor product" irrespective of whether or not there was a link to a pharmaceutical company [20] .

39. While this point is not of relevance to the case of the Executive Director examined above (since he never owned *any* of the patents in question), the Ombudsman takes this opportunity

to suggest that EMA make changes to these rules.

40. Patents can cover a vast diversity of inventions, from machinery to software, from chemicals to pharmaceuticals. Their content is limited only by human imagination and ingenuity. Clearly, if an EMA staff member owns a patent in an area which has no connection with the work of EMA, the staff member need not declare that patent ownership to EMA. Such ownership could not compromise that person's independence as an EMA employee.

41. However, if a person owns a patent **in the area of pharmaceutics** , it is important for EMA to know that. Certain activities of EMA will have a (positive or negative) impact on the value of patents related to medicinal products, regardless of whether a patent has a link to a specific pharmaceutical *company* . The fact that a pharmaceutical company may not (yet) have shown an interest in exploiting the patent (by buying it or obtaining a licence to use it) should not imply that the ownership of the patent **in the area of pharmaceutics** need not be disclosed to EMA.

42. The Ombudsman thus suggests that EMA should not limit the declaration requirements to ownership of patents with a link to a pharmaceutical company. She suggests that EMA's declaration requirements include all patents related to **medicinal products or uses of such products** , that is, all patents **relevant** to the pharmaceutical industry, which is the regulatory field of activity of EMA.

43. It would also be prudent to amend the rules to ensure that relevant patent *applications* **pending at the time the staff member takes up employment at EMA are declared** , where the staff member is one of the applicants. Patent applications can be financially exploited (for example, they can be sold). Their value can be influenced by the regulatory work of EMA. For example, if the patent application relates to a new avenue to exploit a pre-existing medicine, the authorisation of that medicine by EMA could influence the value of the patent application. Thus, it may also be prudent for staff members to declare any relevant **pending patent applications** they have when they join EMA.

44. This does not mean that any interests based on intellectual property rights in the pharmaceutical industry must automatically be considered incompatible with a staff member's involvement in any of EMA's activities. Although all such interests should be **declared** , it is likely that in most cases the only necessary restriction arising from such an interest is that the staff member should be prohibited from being involved in any specific activity linked to the intellectual property at stake (the Ombudsman notes again that, in this case, the Executive Director did not have any such interests to declare).

45. EMA's current rules do not require a staff member to declare the ownership of a patent if the staff member is no longer owner of that particular patent when taking up his or her duties with EMA [21] . This is understandable; a staff member will generally eliminate any risk of a conflict of interests arising in relation to patents if he or she disposes of any patent rights **before joining EMA** .

46. However, the present case illustrates why it may be wise to provide information about a staff

member's prior ownership of patents and patent applications. Certain public records seemed, at first sight, to indicate that EMA's Executive Director had been awarded a patent in 2012. In light of this limited information, it is understandable that members of the public can have certain concerns. While the Ombudsman's detailed inquiry served to obtain the clarifications necessary to establish that the Executive Director did not own a patent in 2012, and did not fail to declare any relevant interests, it is important for EMA to avoid, to the greatest extent possible, such concerns from ever arising. This will also serve to protect the legitimate interests of EMA's staff.

47. The Ombudsman thus suggests that EMA amend its rules so as to require staff to declare all patents relating to medicinal products or uses of such products which have been **owned at some point during the five years** preceding the start of the employment at EMA. If such rights were disposed of or lapsed in that period, this should be noted in the declaration of interests. It should also be noted when, and to whom, any rights were transferred. The very same principles should apply to **patent applications** in the area of pharmaceutics.

48. After all, doubts among the public are much less likely to arise if interests—even those that are unlikely to give rise to any conflict—are openly declared and, if necessary, managed, rather than if EMA is forced to explain, in hindsight, why certain interests did not have to be declared.

Conclusion

Based on the inquiry, the Ombudsman closes this case with the following conclusion:

There was no maladministration by the European Medicines Agency.

The complainant and EMA will be informed of this decision **.**

Suggestions for improvement

The Ombudsman suggests that the European Medicines Agency amends its rules so as to require its staff to declare all current intellectual property rights, such as patent ownership and patent applications, related to medicinal products or uses of such products.

The Ombudsman suggests that the European Medicines Agency amends its rules so as to require staff to declare intellectual property rights related to medicinal products or uses of such products owned during the five years preceding the start of their employment at the European Medicines Agency. Such declarations should also cover patent applications.

Emily O'Reilly

European Ombudsman

Strasbourg, 22/11/2017

[1] When EMA sent its reply to the complainants, its own rules were set out in its Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members of the European Medicines Agency and candidates before recruitment, EMA/622828/2013 Rev. 1.

[2] Article 75 of Regulation 726/2004 (Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ 2004 L 136, p. 1, consolidated version available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0726:20120702:EN:PDF [Link]).

[3] Articles 11-26a of the Staff Regulations (Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community, OJ 1962 P 45, p. 1385, consolidated version available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01962R0031-20160101 [Link]).

[4] Article 11 of the Staff Regulations.

[5] Article 11a(1) of the Staff Regulations.

[6] The current rules are set out in Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members of the European Medicines Agency and candidates before recruitment (“EMA’s decision on the handling of declared interests”), EMA/259494/2016, available at: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/11/WC500216191.pdf [Link]

[7] Article 2 of EMA’s decision on the handling of declared interests.

[8] Article 3 of EMA’s decision on the handling of declared interests. Interest level 3 if the staff member or candidate has declared direct interests; interest level 2 if the staff member or candidate has declared indirect interests; interest level 1 if the staff member or candidate has not declared any direct or indirect interests.

[9]

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000112.jsp&mid=WC0b01
[Link]

[10] Page 16 of EMA's decision on the handling of declared interests.

[11] Based on the rules provided for in Article 63(2) of Regulation 726/2004: " *Members of the Management Board, members of the committees, rapporteurs and experts* **shall not have financial or other interests in the pharmaceutical industry** *which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All* **indirect interests which could relate to this industry** *shall be entered in a register held by the Agency which is accessible to the public, on request, at the Agency's offices* " (emphasis added).

[12] Implementing rules relating to Articles 11a and 13 of the Staff Regulations concerning the handling of declared interests of employees of the European Medicines Agency.

[13] Article 9 of EMA's decision on the handling of declared interests (see footnote 6).

[14]
https://www.iprhelpdesk.eu/kb/2593-whats-difference-between-inventor-applicant-and-owner-patent
[Link]

[15] See, for example, Section 6(1) of the Austrian Patent Law 1970: " *Employees shall also be entitled to the grant of a patent for inventions made during the term of their employment (section 4), unless stipulated otherwise by agreement* [...]", available at:
https://www.patentamt.at/fileadmin/root_oepa/Dateien/Patente/PA_Gesetze/PatG_englisch.pdf
[Link] .

[16] See, for example, Section 39 of the UK Patents Act: " *Notwithstanding anything in any rule of law, an invention made by an employee shall, as between him and his employer, be taken to belong to his employer for the purposes of this Act and all other purposes if* [...] *it was made in the course of the normal duties of the employee* [...] *and the circumstances* [...] *were such that an invention might reasonably be expected to result from the carrying out of his duties* [...]",
available at:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/647792/Consolidated_Patents_Act_1
[Link]

[17] In the US, the Executive Director was also one of the initial co-applicants since, according to US law until 2012, only the patent inventor could make a patent application. In this case, the rights to the patent application were assigned to the pharmaceutical company during the processing of the application. For more information, see:
https://www.uspto.gov/web/offices/pac/mpep/s60sa5.html [Link]

[18] Again, in the US, the Executive Director was also one of the initial co-applicants (see footnote 17).

[19] Page 8 of the Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members of the European Medicines Agency and candidates before recruitment, EMA/259494/2016, available at: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/11/WC500216191.pdf [Link]

[20] Page 7 of the Implementing rules relating to Articles 11a and 13 of the Staff Regulations concerning the handling of declared interests of employees of the European Medicines Agency.

[21] Page 10 of EMA's decision on the handling of declared interests.