

## DISCUSSION PAPER

### Pharmaceutical Industry Scenarios and Questions Relating to Patent Disclosure

European Federation of Pharmaceutical Industry Associations (EFPIA)

#### Scenario 1

1. Company A is informed that rubbing a bruise with a leaf from the XYZ tree in Brazil alleviates bruising. It obtains the seeds (with appropriate consent) and grows sufficient quantities to enable it to extract and purify the oils which it then sells. It patents the purified oils, their use and the process of extraction and purification. Would the disclosure requirement apply?
2. Company A is informed that rubbing a bruise with a leaf from the XYZ tree in Brazil alleviates bruising. It obtains quantities of the leaves (with appropriate consent) and isolates and synthesises the active ingredient which it develops and then sells. It patents the active ingredient and its use. Would the disclosure requirement apply?
3. Company A obtains (with appropriate consent) leafs from 100 species of trees in Brazil. It knows nothing about their properties. Using various assay techniques, it discovers that one ingredient of one of the leaves is medically useful. It isolates and synthesises the active ingredient which it develops and sells. It patents the active ingredient and its use. Would the disclosure requirement apply?
4. Under 3, does it make a difference to the applicability of any disclosure obligation if the medical use was known to a community in Brazil but not disclosed to Company A either at the time of collection or before application for the patent?
5. Company A does either 2 or 3 but finds that the ingredient it has isolated and synthesised has unacceptable toxicity. It finds a hitherto unknown analogue of it in the same class of compounds and patents and commercialises that analogue. Would the disclosure requirement apply?
6. Company A does 2, 3 or 5 but does not commercialise the product. On the basis of the patent disclosures of Company A, Company B develops, patents and commercialises a compound in a different class of compounds from those patented by Company A. Is there a need for Company B to disclose the origin of the leaf used by Company A? Does it make a difference if Company A had disclosed its origin?

#### Scenario 2

One of the thousands of compounds synthesised by Company A as part of its combinatorial chemistry program is Compound X. Its screening processes disclose that this novel compound has a medical use. It patents the compound and its use. However, Company A cannot develop a cost-effective method of producing commercially-viable quantities of the compound and does not commercialise it.

Company B is aware of the patent disclosure. It obtains access to a large number of micro-organisms from Brazil and discovers (it is not told) that one of them naturally produces Compound X, but not on a commercially efficient scale or with adequate purity.

Based on this discovery, it analyses a similar micro-organism which is native to Europe and finds that that micro-organism produces Compound X more efficiently than either the micro-organism from Brazil or the synthetic route disclosed in Company A's patent.

Company B genetically modifies the European micro-organism to improve production efficiency still further. It patents the micro-organism and compound X as produced by the micro-organism.

Company C genetically modifies the European micro-organism still further to improve the purity of Compound X and obtains relevant patents.

Companies A,B and C cross-licence each other under the patents to enable sale of the commercial products.

Does Company A, B or C have to disclose the Brazilian micro-organism?

### Scenario 3

1. Company D is informed that people wash clothes with a plant extract from Chile. It obtains the plant (with appropriate consent) and discovers a new lipase enzyme. It isolates the gene for the enzyme and patents the isolated enzyme, its DNA sequence, its use in laundry detergents and a process for its recombinant production. Would the disclosure requirement apply?
2. Company D is informed that people wash clothes with a plant extract in Chile. It obtains the plant (with appropriate consent) and discovers a new lipase enzyme, isolates its gene, and determines its DNA sequence. The company finds, however, it cannot withstand normal laundry temperatures, and publishes the work. Company E reads the publication and undergoes extensive R&D to mutate the gene to make the gene more heat stable. The new gene shares only 40% sequence identity with the original gene. Company E patents the mutated enzyme, its gene sequence, its use in laundry detergents and a process for its recombinant production. Would the disclosure requirement apply?
3. Under 2, does it make a difference to the applicability of any disclosure obligation if (i) Company D worked with Company E to generate the new enzyme and a joint patent application was filed? (ii) Company E later exclusively licenses Company D to make and sell the enzyme in washing powder? (iii) Company D did not publish, but gave Company E the information under a contractual obligation to pay royalties to Company D should a commercially viable enzyme be marketed.
4. Under 2 or 3, does it make a difference to the applicability of any disclosure obligation if Company D never discloses to Company E the source of the plant, and the plant is also found to be native to the country of Company D and Company E.

#### Scenario 4

1. Company F is informed that a plant virus is wiping out a cash crop native to Bolivia. The company obtains the plant (with appropriate consent) and discovers a receptor which the virus uses to infect the plant. The DNA sequence of the receptor is found and the receptor is cloned and used to screen compound libraries for chemical antagonists which would prevent viral infection. A patent application is filed on: the new receptor, its gene sequence, methods of finding antagonists, the chemical antagonists themselves, and their use. Would the disclosure requirement apply?
2. Under 1, does it make a difference to the applicability of any disclosure obligation if the receptor was found by the Bolivian Agricultural Department, and its sequence published, and i) Company F was given the vector comprising the gene for the receptor by the Bolivian Agricultural Department and the antagonists were found and patented?, or ii) Company F synthesised the published gene sequence to discover and patent the antagonists?

#### Scenario 5

Consider all of the above cases and assume that, for whatever reason, relevant patents are held invalid. Producers of generic/unpatented products make large amounts of money selling the products. Are those producers obliged to share the benefits of their sales with the countries which provided the materials?

#### Scenario 6

In order to make a wheat crop more hardy, plant breeders crossed a conventional wheat variety with a variety obtained from Russia (with appropriate consent). Plant Breeders Rights were obtained (under UPOV) for the new variety. Would the disclosure requirement apply? What if several breeding steps were required to generate the new plant variety, and the Russian variety had been used 20 steps previously to the new variety being generated?