



ELMC Case M-20/21

Anato v State of Confinia and Fonda &

Isaa and Maryam v State of Confinia

The Road to Europe

1. Isaa and Maryam are high school sweethearts from Damsco, the capital of Ebernaria, a country outside the European Union (*EU*) situated in a region plagued by civil and political unrest. In 2016, the very year that they were supposed to obtain their bachelor's degree, a horrible civil war between the forces of the cruel dictator Ghadossam, and separatist rebels, the Cortistas, forces them to flee their beloved home country and leave for Cedaria, another third country, neighbouring Ebernaria.
2. After three years in legal limbo in Cedarian refugee camps, Isaa and Maryam decide that they want to try to reach the EU. The nearest EU Member State is Confinia, a small Member State that joined the EU in 2009. Confinia's population currently makes up no more than two percent of the EU's citizenry. It is known for its wonderful wine, heart-warming hospitality and its badly run administration. Being a country at the borders of Europe, Confinia has seen many refugees seek asylum within its borders.
3. Given the political tensions this situation has caused, and the precarious economic position in which Confinia finds itself, its government has been pushing a "reception in the region" agenda at EU level, aimed at providing care for refugees closer to their country of origin. Of all the Member States, Confinia has one of the strictest applications of the EU's asylum rules. At the same time, it does try to balance its restrictive policy somewhat by allowing for legal pathways to asylum. It has, for example, recently established a national humanitarian visa scheme for third-country nationals who wish to travel to Confinia for the purpose of requesting asylum. In addition, Confinia is the most generous Member State in terms of the number of refugees it accepts for resettlement.
4. While still in Cedaria, Isaa and Maryam decide to explore the legal ways to reach Europe. They first register with the United Nations High Commissioner for Refugees' (*UNHCR*) office in LaBoom, the capital of Cedaria, in order to be considered for resettlement in Confinia. Unfortunately for them, they do not fall within the category of vulnerable refugees to whom priority is given. Subsequently, therefore, they decide to request a humanitarian visa at the Confinian consulate in Cedaria. This visa would enable them to travel to Confinia to request asylum there. Alas, Confinia limits the number of visas issued under this scheme to 7,500 people per year, and by the time Isaa and Maryam file their application in March 2019, that number is long filled. Once again they are not considered sufficiently vulnerable to be given priority under the applicable exceptions under the scheme.



5. Early in 2020, the situation in the refugee camps in Cedaria rapidly deteriorates. Increasingly desperate, Isaa and Maryam turn to human smugglers to get them across the border with Ottonia. Ottonia, situated between Cedaria and Confinia, is one of the largest third countries neighbouring the EU. Once in Ottonia, the long road to safety continues on foot, by train and hidden in the back of a minivan. Still, the most dangerous part is yet to come: the border crossing from Ottonia into Confinia requires navigating a snowy mountain pass through the Captonian Mountains, and crossing a wild-running border river, the Styres.
6. Realising their chances of getting asylum in Confinia are slim, Isaa and Maryam intend to travel onwards from Confinia and into EU Member State Mayacuda. From there, they hope finally to reach Battonia. Battonia is a large and relatively wealthy EU Member State, where about 20 percent of the EU's population lives.
7. Isaa and Maryam are not alone on their journey. They are joining an increasingly large number of refugees and migrants trying to make it to the EU, some of whom – like Isaa and Maryam – are fleeing war, but some of whom are also escaping economic hardship and the outbreak of SMERS-20, a mutated and even more dangerous version of SMERS-18. The SMERS (i.e. the Sudden and Massively Enervating Respiratory Syndrome) viruses are highly contagious. SMERS-18 has already caused a massive pandemic resulting in hundreds of thousands of deaths and the halting of public life across the globe.

The EU steps up

8. Meanwhile, the Member States of the EU convene in the European Council to discuss the refugee situation at the EU's external borders, as well as the SMERS-20 threat. Based on a recommendation by the European Commission (**Commission**), the European Council endorses a coordinated approach at the external borders. This approach limits non-essential travel from outside the EU, which it is hoped will help counter the spread of the SMERS-20. This is similar to the action the European Council took a year earlier in response to the outbreak of SMERS-18, an action the media often referred to as the "EU travel ban".
9. The Act of Accession which brought Confinia into the EU, copy-pastes the relevant provisions of the Acts of Accession of the other Member States that joined the EU in the first decade of the 21st century. Although Confinia has long fulfilled the technical requirements to join the Schengen area, the lifting of checks at the internal border has not yet taken place. Confinia will only apply the provisions of the Schengen acquis in full, once the Council has taken a unanimous decision to that effect, and a number of Member States have been blocking the making of this decision for political reasons (mainly related to concerns over corruption and problems with the rule of law in Confinia).
10. As a result, Confinia has been in the Schengen waiting room for over a decade. Neighbouring Member State Mayacuda, itself a full member of the Schengen area for decades, has even started the construction of a fence along its border with Confinia. As an act of political resistance, and



encouraged by its close cultural and historical ties with neighbouring third country Ottonia, Confinia refuses to follow the EU's coordinated approach at the external borders.

11. The European Council calls upon the Commission to bring forward proposals based on article 78(3) of the Treaty on the Functioning of the European Union (*TFEU*) in light of the increasing numbers of refugees and migrants arriving in Europe. Given the urgency required by the situation, the Commission quickly follows up. Based on the Commission's proposals, the Council adopts the following measures:

- **First**, in Council Decision (EU) 2020/1239 (the *Safe Third Country Decision*) the Council labels a number of third countries in the EU neighbourhood, including Ottonia, as safe third countries for the purposes of Directive 2013/32/EU (the *Procedures Directive*);
- **Second**, in order to alleviate pressure on Confinia, it adopts Council Decision (EU) 2020/7890 (the *Relocation Decision*), agreeing to relocate 10,000 refugees from Confinian reception centres. The Relocation Decision is a copy-paste of the similarly worded Council Decisions (EU) 2015/1601 and 2015/1523, with the difference that in practice the eligibility criteria will only apply to Ebernarian refugees. The Relocation Decision will apply until 1 January 2021. Not surprisingly, the Relocation Decision proves to be as controversial as its 2015 predecessors and it only passes with the smallest qualified majority. Mayacuda, obliged to take over 5,600 asylum seekers from Confinia, publicly declares that it does not intend to cooperate; and
- **Third**, the Council adopts Decision (EU) 2020/2031 allowing Member States to temporarily derogate from the right laid down in the Procedures Directive which allows a third country national to lodge an asylum request at the border of a Member State. This derogation applies only where the neighbouring country (i.e. the country from which the third country national is seeking to access the relevant Member State) is either itself a Member State, or is deemed to be a safe third country and such country agrees to accept asylum seekers who are prevented from seeking asylum at the border.

12. Complementing the Council's measures, Confinia concludes a controversial, non-published agreement with Ottonia, negotiated on its behalf by the Commission. Under the "Declaration of Friendship", as the deal between Confinia and Ottonia is referred to in a Commission Press Release, Ottonia agrees to process the asylum claims of all asylum seekers that are turned back at the Confinian border with Ottonia, in exchange for significant financial aid provided by both the EU and its Member States, as well as access to some of the mineral resources found in disputed territory situated in the Captonian mountains. Ottonia will implement the "Declaration of Friendship", in line with the terms of the readmission agreement that it concluded with the EU in 2016, on the basis of which Ottonia will accept back not just its own nationals currently residing irregularly on EU territory, but also irregular migrants that have transited through its territory and are now residing in the EU.



13. Ottonia is not a party to the 1951 Geneva Convention relating to the Status of Refugees, but has enshrined the right to asylum in its constitution. It is also a party to the European Convention on Human Rights (the *ECHR*). Its asylum law gives basic rights to persons officially recognised as refugees, such as the right to schooling and the right to work. Unfortunately, in practice, Ottonia has had a hard time coping with, and providing adequate reception for, the large numbers of refugees on its territory. Consequently, the conclusion of individual asylum procedures can take several years (and is expected to worsen following the adoption of the EU's coordinated approach).
14. Attitudes amongst the population towards refugees in Ottonia have also become increasingly hostile, and reception centres have even been the object of attacks by angry citizens from the 'Make Ottonia Great Again. Again' movement. There are numerous reports from human rights organisations about overcrowding and unsanitary conditions in the reception centres. To make things worse, the outbreak of SMERS-20 has led the Ottonian government to confine all refugees to the premises of the reception centres. Although its own health care system is under considerable pressure, the Ottonian government has made additional resources available for medical care in case outbreaks of SMERS-20 are detected at the reception centres.
15. As Isaa and Maryam finally reach the Confinian border, having crossed the Captonian mountains, they quickly realise that they do not stand a chance of passing through. Indeed they are immediately turned away at the border checkpoint. Based on the deal between Ottonia and Confinia, they are told by the border guards to request asylum in Ottonia or, alternatively, apply for a humanitarian visa at the Confinian Consulate in Ottonia's capital Instapol.
16. Four years after having left their homeland, in **July** 2020, the couple now finds themselves, together with many other refugees, in a no man's land on the Ottonian side of the border. Having come this far, Issa and Maryam are determined to make it into the EU and decide to try and enter Confinia outside the official border crossing point, meaning they will have to cross the Styres river at night. Miraculously, they manage to get across on a makeshift raft, but as they are hiding from the Confinian border patrols, two dogs - a Labrador Collie named Harry and a six-year old Beagle/Labrador cross named Susie (it is only Susie's third patrol, while Harry is shortly due to retire following the development of an untreatable arthritic condition in his left, front paw) - detect Maryam who is arrested and immediately returned to Ottonia.
17. Isaa and Maryam had agreed that if they were to be separated or arrested at any point during their travels, the other would continue on their journey. With a heavy heart, Isaa travels onwards and makes it to the Confinian capital Jakab, where he claims asylum in late July. He is transferred to a reception centre. Isaa hopes that he will be able to benefit from the scheme set up under the Relocation Decision and be relocated to another Member State, hopefully Battonia. However, he is quickly informed by the Confinian authorities that the mechanism is highly dysfunctional. It is not only an administrative nightmare, but quite a few Member States have simply refused to honour the Relocation Decision and are not allowing for the transfer of refugees from Confinia. Consequently, the Confinian authorities have pretty much abandoned all



preparatory work for the operation of the mechanism, especially given that the Decision will expire in a couple of months anyway. As a result, Confinia's reception centres remain overcrowded and the processing of asylum claims have backed up. All Isaa can do at this point is wait.

18. Isaa is shocked to find out that, due to the fear of the spread of SMERS-20, Confinia has locked down all reception centres and only allows asylum seekers to leave the premises of the centre if they agree to wear the FFH Tracking and Diagnostics Bracelet© (the **FFH Bracelet**) with the SMERS-20 software update (the **S-20 Update**) (the FFH Bracelet, when enabled with the S-20 Update, is hereinafter known as the S-20 Bracelet). Isaa is informed that by tracking the location of users, the Confinian health authority is able quickly to identify and isolate any cases of SMERS-20 brought into its territory by non-residents.
19. Asylum seekers must also agree to the terms and conditions which accompany the S-20 Bracelet. These terms and conditions permit, amongst other things, that the tracking data be shared with and used by the immigration department of the Confinian government, and that the health data is made available to health organisations, medical professionals and/or drug manufacturers/developers appointed by the government of Confinia for the purpose of effectively combatting SMERS-20. These data collection measures are part of a broader project instigated by Confinia following the onset of SMERS-20 and come off the back of EU-wide action against SMERS-18.

An (initially) harmonious fight against SMERS-18

20. During the SMERS-18 outbreak, the EU attempted to combat the disease in a coordinated manner. An EU-wide joint research project was set up to develop a vaccine to enable EU citizens to enjoy their rights to work and travel freely within the EU (the Anti-SMERS Project - known as the **AS Project**). The AS Project had been led by the Faculty of Health and Life Sciences of the University of Jakab, and was supported by pharmaceutical producers Anato (incorporated under the rules of and headquartered in Battonia, but with a sales office in Confinia) and Dingue & Darch (incorporated and operating from Mayacuda, **D&D**).
21. The AS Project was funded by the EU on the proviso that data used for this project (including test data) was shared amongst parties through the EU eHealth Network in conformity with Directive 2011/24/EU. It was agreed that the University of Jakab would be the owner of the patent relating to the relevant substance and production method of the to-be-developed vaccine, but that it would provide production licences, know-how and training related to the vaccine throughout the EU on a royalty-free basis. This was designed to enable any party with a legitimate business case to produce the vaccine, allowing both pharmaceuticals and generic drug manufacturers to (mass) produce the vaccine against SMERS-18 and ensure availability across the EU in a timely manner.



22. The vaccine against SMERS-18 that was eventually developed did not provide total immunity to SMERS-18 but rather provided a two-week immunity window (the *S-18 Vaccine*). To ensure that the virus would not mutate in such a way as to build resistance to the S-18 Vaccine, the European Medicines Agency advised in its market authorisation opinion that use of the vaccine was to be restricted to once every three months. It also required that the S-18 Vaccine only be sold as a prescription medicine. The S-18 Vaccine's price, however, was not regulated.
23. EU-wide health campaigns were rolled out to make EU citizens aware of the dangers of overuse, both for one's own health and in terms of the potential for SMERS-18 to mutate in response to the vaccine. During the months immediately following the S-18 Vaccine's release, the vaccine and the related health campaigns appeared to be a success – citizens were using the vaccine conscientiously and only after obtaining the required health consultation. The number of cases of SMERS-18 within the EU dropped massively - after three months, deaths had all but been eliminated, and only a handful of hospitalisations remained. The S-18 Vaccine was particularly popular amongst citizens in Battonia, where Anato quickly gained a good reputation amongst consumers. Following this success, Anato managed to obtain a leading EU-wide position with a 38% market share of sales by volume. This success was due to its well established reputation in the Battonian market, and the harmonisation of regulatory requirements at EU level allowing it to sell the S-18 Vaccine quickly and easily across all Member States. In terms of market share, D&D established itself as the second biggest producer of S-18 Vaccine, with 23% of sales by volume.

Fonda's foot in the door

24. Fonda's Fitness & Health (*Fonda*) also developed a generic version of the S-18 Vaccine.
25. Fonda is a company incorporated under the laws of Ottania but with its EU headquarters and research centre in Jakab, Confinia. Fonda operates the only full-service online health tech platform in Europe. On its platform, Fonda sells branded and generic over-the-counter and prescription medicine through its online pharmacy, apps and wearables through its IT store, and since September 2017 it has also offered health consultation services through its online "general practice", for which Fonda has concluded individual services agreements with medical professionals in every Member State. These professionals offer full health consultation services in an online setting (via webcam). Subscribers to Fonda's online health consultancy service have access to their own profile page through which they can request and access the health consultation services and make purchases. Fonda's services agreement with the medical professionals do not restrict them from prescribing medicine and products from any producer (including competitors) that the professionals consider most appropriate for the treatment of their patients. Fonda does include targeted advertisements for its own products (but not those of competitors) on the users' profile pages. In return, the medical professionals received a small remuneration if a patient actually purchases Fonda's products through clicking on these ads.



26. The online consulting services have proved extremely popular throughout the EU and Fonda considers itself the front-runner and the indisputable market leader in providing these services. Fonda's marketing method also seemed to have paid off. After the roll out of the online health consultation services, Fonda had seen double digit increases in the sale of its own products within a matter of three years.
27. The sale of Fonda's generic version of the S-18 Vaccine has, however, lagged behind. Its sales have never represented more than a 3% market share throughout the EU. Evidence suggests patients have a strong preference to purchase the S-18 Vaccine from the pharmaceutical companies that were originally involved in the AS Project.

Confinia goes it alone

28. Following an initial period of success in suppressing SMERS-18, in January 2020, EU member states gradually began noticing a change in the behaviour of citizens in the use of the S-18 Vaccines. The AS Project had indeed been a success and many pharmaceutical companies had begun the manufacture of the S-18 Vaccine on receipt of the project's results. While helping to subdue the virus, the AS Project had become a victim of this success, and overproduction of the S-18 Vaccine resulted in the development of a black market. The government of Confinia had reports of frequent off-label use and the purchase of the S-18 Vaccine without a prior health consultation became prevalent.
29. As a consequence, in March 2020 fear became a reality and the number of new cases started to increase rapidly. More worryingly, it appeared that the virus had mutated into the much more dangerous SMERS-20 strain. Healthcare professionals quickly found that the S-18 Vaccine only had limited efficacy in respect to SMERS-20. While in some (small percentage of) people it was found that the S-18 Vaccine could induce an immune response that prevented the development of certain SMERS-20 symptoms (i.e. resulting in a less severe form of the disease), for the majority of the population, and in particular for vulnerable demographics, the S-18 Vaccine was (and remains) totally ineffective in preventing the development and spread of SMERS-20.
30. The government of Confinia considers SMERS-20 to be a health emergency and quickly concluded that a rapid response is required. Not waiting for a coordinated proposal from the EU, Confinia instead began its own project to develop a vaccine to counter the newly-emerged virus (the *S-20 Vaccine*). To achieve this, the Confinian Government brought the University of Jakab together with Fonda (which it considers to be a good pharmaceutical candidate given its all-round services and the location of its research centre in Jakab, helping to ensure that the project is smoothly and efficiently managed). Fonda is thrilled to participate in the research project, believing that it can use its participation in the project to boost its reputation as a drug producer amongst consumers of its health consultation services, helping to sell the S-20 Vaccine and potentially also improve sales of its generic S-18 Vaccine variant.



31. And so, the Fonda/University of Jakab Project was born (the *FUJ Project*). Under the deal creating the FUJ Project, the following was agreed:
- a. Fonda and the University of Jakab will work together on an exclusive basis to develop the S-20 Vaccine;
 - b. In order to accelerate the data collection required for the research, Fonda will develop the S-20 Update for the FHH Bracelet, resulting in the S-20 Bracelet. The S-20 Bracelet should collect health data from users and be able to detect other devices that have been within a certain distance for even a limited duration;
 - c. The Confinian Government will adopt a Decree, in which is confirmed that, in the interest of public health and safety, (i) persons residing in Confinia above the age of 12 (including refugees) are obliged to wear the S-20 bracelet and to allow for the processing of their personal data by Fonda and (ii) Fonda is allowed to collect and process the data it gathers for the purpose of combatting SMERS-20 and not for other (marketing or business) uses. Confinia cites the exception mentioned Article 23 of the EU Regulation 2016/679;
 - d. Fonda will offer the S-20 Bracelet free of charge in exchange for the user agreeing to enable the tracking application which gathers the data required for its research;
 - e. Finally, in order to ensure that overuse of any subsequently-produced S-20 Vaccine is prevented, it is agreed that while the University of Jakab will (again) become the owner of the relevant patents, Fonda shall obtain the exclusive non-transferable right to produce and to sell the S-20 Vaccine on its platform, and only where a health consultation has confirmed that use is required.
32. Following the initiation of the FUJ Project, Fonda quickly develops the S-20 Update, allowing the S-20 Bracelet to capture all the data required by the FUJ Project agreement. For its part, the Confinian Government releases the relevant decree on 1 May 2020, the same day that the S-20 Bracelet is first available.
33. The bracelet works together with an app installed on any smartphone. It collects the user's name, phone number and IP address and detects and records health data, including activity levels, heart rate, temperature and respiratory data, including breaths per minute but also coughing, shortness of breath, wheezing etc. It is also able, through Bluetooth technology, to network with other S-20 Bracelets, showing how long a person has been close to another app user thereby greatly assisting in the track-and-trace operations health experts suggest are necessary for containing the virus (despite the downplaying of this by some right-wing populist leaders). The data is stored on servers in Confinia and is used by the FUJ Project to develop tailored treatment for SMERS-20, and the development of the S-20 Vaccine.
34. As a result of the obligatory use of the S-20 Bracelet in Confinia, around 8 million persons in Confinia are using the device since its launch in May 2020. The bracelet has been a surprisingly



great success outside Confinia as well. Over 150 million persons residing in other EU member states are making use of the S-20 Bracelet after Fonda extended across the EU its offer to provide the bracelet for free, in exchange for users agreeing to allow the processing of their data for the benefit of the development of the new vaccine. While the collected data is in principle anonymised, users are incentivised to disable the anonymisation through the offer of discounted additional online health care on Fonda's platform and free SMERS-20 personal protective equipment (masks, sanitisers, disinfectants etc). More than 80 percent of users have voluntarily opted for this.

35. The user data has already shown to be very effective for the monitoring of the physical condition of the wearer, warning him/her of the onset of early symptoms indicating a SMERS-20 infection. The data has also allowed health authorities quickly to locate and respond to localised outbreaks of the SMERS-20 and it provides the FUJ Project with detailed insight in mapping the symptoms and patient responses to certain medication.
36. The data captured by the S-20 Bracelet proves to be invaluable for the development of the S-20 Vaccine also. By Mid-June 2020, the FUJ Project had produced a viable vaccine candidate, and by the end of July 2020 it had successfully completed clinical trials. The FUJ Project participants and the Government of Confinia, thrilled with the results, apply for market authorisation for the new vaccine on 3 August 2020. Fonda and Confinia subsequently agree on a contractual framework for the purchase of 15 million doses of the S-20 Vaccine, with an option to purchase 20 million more. Fonda is also approached by a number of other Member States which wish to enter into similar agreements.
37. Since the identification of SMERS-20, Anato has also been trying to develop a new vaccine at its laboratories in Battonia - thus far unsuccessfully. It is clear to Anato that it has insufficient user data to run the tests and analyses needed for the development of such a vaccine. It therefore approaches Fonda to reach an agreement on the sharing of the FUJ Project's data pool and research results. Anato's approach to Fonda is met with an outright refusal. Fonda believes that the agreement governing the FUJ Project does not allow it to provide such data, even if it should want to. On top of that, since June 2020, despite its S-18 Vaccine being successfully used to limit symptoms for a small percentage of SMERS-20 patients, Anato has seen a dip in the sales of its vaccine via Fonda's platform. Anato has the suspicion that Fonda may have been using the data it is collecting to persuade patients of its health consultation services to purchase Fonda's S-18 Vaccine, to the detriment of Anato.
38. In light of this, Anato decides it wants to file a complaint with the Confinian Competition & Consumer Commission (the *CCCC*). Anato reaches out to Alix, who is of Battonian origin, but has been working as a lawyer in Confinia for over two decades. She has a well-established track record in competition and antitrust law. Alix files the complaint with the CCCC on Anato's behalf. This complaint alleges that Fonda is using the user data it collects through the S-20 Bracelet to cement its position in the marketplace, and that the agreement between Confinia and Fonda results in abuse of dominance. The CCCC asks for information from Fonda, the Ministry



of Health and the University of Jakab on the alleged conduct, but eventually decides to refuse to take up the complaint. It explains that: (i) the alleged infringement falls outside its enforcement priority; and (ii) on the basis of responses received from its information requests, it has concluded that there is no prima facie infringement and the FUJ Project agreement appears to be objectively justified for grounds of public order.

Confinia's SMERS-20 response checked

39. Desperate to keep its business afloat, Anato asks Alix to initiate proceedings against Fonda and the State of Confinia at the District Court of Jakab. In the case *Anato vs. State of Confinia and Fonda*, the District Court is requested to order:
- i) Fonda to provide access to the user data set and its research results;
 - ii) alternatively, the FUJ Project to be altered to allow for the sharing of such data;
 - iii) in the further alternative, Fonda to share the software for the S-20 Update to enable other market players to develop their own data collection device; and
 - iv) payment of damages to Anato for current loss in sales due to the targeted advertisements on Fonda's platform resulting in decreased sales of its S-18 Vaccine, as well as future loss relating to its delayed ability or inability to develop a vaccine.
40. Anato argues that the dataset held by Fonda is non-replicable and that by withholding this data set and/or the S-20 Update used to collect this data from other manufacturers, it is made impossible for other market players to develop their own vaccine against SMERS-20. Moreover, Anato alleges that Fonda further illegally compromises Anato's position by misusing the S-20 Bracelet user data to induce patients to buy Fonda products and that the State of Confinia has endorsed Fonda's behaviour by facilitating the collection and processing of this data by Fonda on an exclusive basis.
41. Alix not only has an impressive career in competition law, but she is also considered an authority in other areas of administrative law - for instance she has represented climate activists against the State on several occasions. The "New Europeans Welcome" collective, an NGO supporting refugees and irregular migrants across the European Union, reaches out to Alix and asks her whether she is also willing to take on Isaa's case. Alix is very happy to take on this case pro bono. She is put in contact with Isaa and learns all about his arduous journey and of his beloved Maryam who is withering away in an Ottonian refugee centre.
42. Alix brings a claim against the Confinian state before the migration chamber of the District Court of Jakab. She does so not just on Isaa's behalf, but also on behalf of Maryam. In the case of *Issa and Maryam v the State of Confinia*, Alix requests the court to order that:



- i) Isaa immediately be allowed to leave the confines of the reception centre and that he be transferred to another Member State on the basis of the Relocation Decision;
 - ii) Issa's confinement to the reception centre constitutes grave violations of his rights under the Charter of Fundamental rights, in particular his right to freedom, physical integrity and right to data protection; and that
 - iii) Confinia accepts **to process** Maryam's asylum claim and pays damages for the violation of her fundamental rights at the hands of the Confinian border guards, in particular the prohibition of non-refoulement and the prohibition of collective expulsions.
43. As both Anato's case and the case of Isaa and Maryam raise important questions touching upon the compatibility with EU law of Confinia's measures in response to SMERS-20, it is decided to join the two cases and allocate the joined cases to the constitutional chamber of the District Court of Jakab. The District Court decides to stay proceedings and submits the following questions to the Court of Justice of the European Union in a preliminary proceeding under Article 267(2) TFEU:
- 1) In light of the facts of this case, should Article 102 TFEU be interpreted to mean that:
 - a) an undertaking is holding a dominant position where it has taken preparatory steps to market a new medicinal product and has exclusive access to a dataset which is required for the development of that product?
 - b) if such an undertaking is assumed to be in a dominant position, its refusal to share this dataset and/or the method of data collection with other market players constitute(s) abusive behaviour in violation of article 102 TFEU?
 - 2) In light of the facts of this case, does EU law, in particular EU asylum law and the provisions of the Charter of Fundamental Rights:
 - a) allow a Member State immediately to return a third-country national who is apprehended during the act of crossing the external border irregularly or shortly thereafter, without allowing that person to lodge a request for international protection?
 - b) oblige a Member State to relocate an asylum seeker to another Member State?
 - c) allow a Member State to confine asylum seekers to reception centres and/or oblige an asylum seeker to wear a tracking device in light of a health emergency?
44. The order for reference was received by the Registrar of the Court, who assigned it case number M-20/21. In accordance with article 23 of the Statute of the Court of Justice, the Registrar notified the parties. Observations are invited to be received by the Court by December 15th, 2020.