Vakıf Medeniyetimizde Darüşşifalar

Doç. Dr. Ahmet AKMAN*

Özet

Günümüzde yaşanan virüs salgınına İslam ve Türk hukuk tarihi perspektifinden baktığımızda Darüşşifaların önemli fonksiyonlar icra ettiğini görürüz. İslam tarihinde konunun Hz. Peygamber'den itibaren özellikle salgın boyutundaki vak'alara ilişkin bugüne de ışık tutabilecek ölçüde bulaş tehlikesine karşı tedbirler alınmıştır. Bu tedbirlere Hz. Peygamber sonrası dönemde de riayet edildiğini görüyoruz. Hz. Ömer'e Şam'da veba çıktığı haberi verilince vebanın olduğu yere gitmemiş, kendisine, "*Allah'ın kaderinden mi kaçıyorsun?*" sorusuna Allah'ın kaderinden yine O'nun kaderine sığındığını cevabını vermiştir. (*Buhârî, Ṭıb 30; Müslim, Selâm 98-100*) Salgın olan yere yaklaşmamak ve salgın olan yeri terketmemek, bu tedbirler arasında bugün de benzer şekilde görülen sosyal mesafe ve karantina altında kalmak tedbirlerine oldukça benzer yönleri bulunmaktadır. 749 (1348) yılında geniş bir coğrafyaya yayılan tâun sırasında Şam şehri ve yakınlarında günde 300'den fazla insanın öldüğünü, sadece Emeviyye Camii'nde bir vakitte on beş kişinin cenaze namazının kılındığını kayıtlarda geçmektedir. Osmanlı döneminde salgın bulunan yeri terk konusunda hukukçuların eserlerinde çeşitli tartışmalara rastlanır. 16. Yüzyıldan sonra bulaşıcı hastalık olan bölgeden havası daha temiz bölgelere intikalin cevazıyla ilgili fetvalar verilmiş olduğunu gibi, salgından kaçarak görevini yerine getirmeyen kamu görevlilerine de ta'zir ve azil cezaları verilmiştir. İslam dünyasında ilk darüşşifa 707 yılında Emevi Halifesi Velid b. Abdülmelik tarafından kurulmuştur. Bundan sonraki dönemlerde bîmaristan ve darüşşifa olarak sağlık hizmetleri belli ölçüde kurumsallaşmıştır. İlk Selçuklu eserinin de Nizamülmülk tarafından Nişabur'da

* Necmettin Erbakan Üniversitesi Hukuk Fakültesi Öğretim Üyesi
aakman@erbakan.edu.tr

kurulduğunu görüyoruz. Yine Bağdat'da 1066'da Nizamiye Medresesi ve Hastanesi bunu takip etmiştir. Sonrasında Harran ve Mardin'deki hastanelerinin de içinde olduğu birçok şehirde benzer darüşşifaları görüyoruz. Anadolu Selçuklularında da bu atılımın sürmesi ile yine birçok yerleşim yerinde bölgesel hizmet kabiliyeti de olan darüşşifaları görmekteyiz. Bunlar arasında en bilinenlerinden olarak Kayseri Gevher Nesibe, Sivas Keykavus ve Konya Alaeddin darüşşifaları zikredilebilir.

Bu darüşşifaların kuruluş ve işleyişlerinde İslam tarihinde önemli bir yer tutan vakıf medeniyetinin izlerini görmek mümkündür. Birçok alanda vakıf yoluyla kamu hizmeti yerine getiren vakıflar, sağlık alanında özellikle devletin önemli ölçüde yükünü almış görünmektedir. Bu müesseselerin vakıf yoluyla sürdürülebilirlikleri sağlanmıştır. Vakıf hukukunda kuruluş ana statüsü olan vakfiyelerde vakfın kurucusunun iradesi çok önemli yer tutar. Vâkıfın ortaya koyduğu şartlar şâriin (*kanun koyucunun*) nassı gibidir. Bu vakfiyelerde özellikle gelirlerin neler olduğu ortaya konurken, bir hastane kurumu düşünüldüğünde harcama yerleri de detaylı ortaya konmak durumundadır. Darüşşifaların işletmesi için gereken kaynağın tedariki bakımından han, hamam, ürün veren arazi işletmeleri türündeki gelir getirici *müsteğallat* ve *müsakkafat* belirtilir. Sonraki dönemlerde de vakıf kurucusu yahut başkalarının bu amaçla tasarrufta bulunmaları hep görülen hususlardandır. Bunlar vakfiyelerin kadı sicillerine tescili ile ve ayrıca bu belgelerde şahitlerin (*şühûdu'l-hal*) imzaları ile kayıt altına alınırdı. Ayrıca bu gelirlerin *câbiler* tarafından toplama usulleri, kimlerin vakfın amaçlarına uygun olarak bu gelirlerden harcama yapacakları vakfiyelerde açık olarak belirtilmekteydi. Hazırlanan vakfiyelerde darüşşifanın işleyiş şekli kesin kurallara bağlanırdı. Vakfiye artık o hastanenin tüzüğü mesabesindeydi. Vakıf mütevellileri sistemin idaresinden sorumlu oldukları kadar, görevliler üzerinde iç kontrol mekanizmasını sağlamakla da yükümlüydüler. Ayrıca genellikle mütevelliden farklı bir kişi olarak, nazır adı verilen bir kontrol görevlisi de bu konuda daha özel bir misyon üstlenmişti. Hastanenin düzeni ve işletilmesinden esasen mütevelli sorumlu olup, bu şahıs vakıf kurucusunun güvendiği ve işin ehli bir kimse olmak durumundadır. Vakfiyede sonraki mütevelliler için açık ve bağlayıcı bir tanımlama yapılmamışsa bu konuda yetki mahkemede olmaktadır. Mütevelli ayrıca hastalıkların teşhisi ve tedavisi

konusunda gereken tedbirleri almakla yükümlüdür. Bunlar yapılmadığında vakfın amacına uygun davranılmış olmaz. Konunun vakıf darüşşifa ilişkisini ortaya koymak bakımından vakfiyeler en temel hukuki belgelerdir.

Anahtar Kelimeler: Darüşşifa, Bîmaristan, Salgın, Tedavi, Hekim.

"DARÜŞŞİFA" IN OUR FOUNDATION CIVILIZATION

Abstract

When we look at the current virus outbreak from the perspective of Islamic and Turkish legal history, we see that Darüşşifa performs important functions. Since the Prophet, precautions have been taken against the risk of transmission, especially to the extent of epidemic cases, to shed light on the present day. We see that the precautions were followed in the post-prophet period. When Ömer was informed that the plague had happened in Damascus, he did not go to the plague, he said to him, "Are you running away from the fate of Allah?" He replied to the question of the fate of Allah that he took refuge in His fate again. Not approaching the place where it was epidemic and not leaving the place where it was epidemic, and these measures are quite similar to the social distance and quarantine measures that are similar today. It is recorded in 749 (1348) that during the taun, which spread over a wide geography, more than 300 people died a day in Damascus and its vicinity, and that the funeral prayers of fifteen people were performed at a time only in the Umayya Mosque. There are various discussions in the works of lawyers about leaving the place that was found to be epidemic in the Ottoman period. After the 16th century, fatwas were given about the answer of the transfer from the region, which has an infectious disease, to the areas with cleaner air, as well as public officials who have not been able to fulfill their duties by escaping from the epidemic have also been punished like ta'zir and dismissed. The first darüşşifa in the Islamic world in 89 (707), was founded by Velid b. Abdülmelik Umayyad Caliph. In the following periods, health services have been institutionalized

to a certain extent as bimaristan and darüşşifa. We see that the first Seljuk work was also founded in Nishapur by Nizamülmülk. Again, in 1066, Nizamiye Madrasa and Hospital followed this in Baghdad. Afterwards, we see similar hospitals in many cities, including their hospitals (darüşşifa) in Harran and Mardin. With this breakthrough in the Anatolian Seljuks, we see darüşşifa, which also has regional service capabilities in many settlements. Among the most well-known among these, Kayseri Gevher Nesibe, Sivas Keykavus and Konya Alaeddin hospitals can be mentioned.

It is possible to see the traces of the waqf civilization which played an important role in the history of Islam about the establishment and the running of these hospitals. The foundations that perform public service through foundations in many areas seem to have taken a significant workload on the state, especially in the field of health. Sustainability of these institutions was ensured through the foundation. The founder's will has a very important place in the foundation law, which is the main status of the waqf. The conditions set forth by the foundation is like the rule of the legislator. In these foundation conditions documents (vakfiye), especially when it comes to revealing what the incomes are, considering as an hospital institution, spending places also have to be revealed in detail. In terms of procuring the resources required for the operation of the darüşşifa, the income-generating of the type of inns, baths, and land enterprises that produce products are specified. It is always seen that the founder of the foundation or others donate for this purpose in the following periods. These were registered in the court records of the foundations and also by signing by the witnesses in these documents. In addition, the method of collecting these revenues by the authorities (câbi) was clearly stated in the foundations to whom they would spend from these revenues in accordance with the aims of the foundation. In the prepared foundations, the way the hospital was operated was bound by strict rules. The foundation was now on the basis of that hospital's charter. Foundation trustees (mütevelli) were responsible for ensuring the internal control mechanism over the officials as well as for the administration of the system. In addition, as a person different from the trustee, a control officer, called nâzır, had undertaken a more specific mission in this regard. The trustee is mainly responsible for

the layout and operation of the hospital, and this person has to be trusted by the founder and competent. If there is no clear and binding definition for subsequent trustees in the foundation, the authority must be in court. The trustee is also obliged to take the necessary measures for the diagnosis and treatment of the diseases. When these are not done, the purpose of the foundation will not be treated. The foundation conditions documents (vakfiye) are the most basic legal documents in order to reveal the relationship of the subject matters to the foundation hospital.

Key words: Hospital, Bîmaristan, Epidemic, Treatment, Medical Doctor.

I- GİRİŞ

İslam medeniyeti içerisinde vakıf kurumu gelişme ve olgunlaşmasına paralel olarak sağlığı da kendisine bir hizmet alanı olarak seçmiştir. Selçuklular döneminde sağlık alanında özellikle önemli kurumsallaşma adımları atılmıştır. Bu dönemde klasik teşhis-tedavi konseptini besleyecek şekilde tıp eğitimi faaliyetleri de sisteme önemli ölçüde entegre olmuş ve bu yönde giderek daha fazla adımlar atılmıştır. Darüttıp adı verilen eğitim kurumları ile sistem bütünleşik hale gelerek, teori ve pratiğin yan yana gittiğine şahit olunur. Selçuklular döneminde dârülâfiye, dârüşşifa, bîmaristan olarak da isimlendirilen sağlık kamu hizmetinin toplumsal hayatta ortaya çıkışı İslam tarihinde daha eskilere dayanır. Bu anlamda ilk bîmaristanın Hendek savaşı yaralıları için oluşturulan seyyar hastaneye atfedilmesi söz konusudur. Dârüssıhha, mâristan, şifahane ve ayrıca başka isimlendirmeler de söz konusudur. *Hastahane* şeklindeki ilk kullanımı Ahmet Vefik Paşa tarafından yazılan Lehçe-i Osmanî'de göze çarpar.[1] Bunun ilk uygulaması bugün de işlevini sürdüren 1845 tarihinde inşa edilen Bezm-i Âlem Vakıf Gureba hastanesinde görülür.

1 Songur, Haluk/Saygın, Tuba, "Şifahaneden Hastaneye" Sağlık Kuruluşlarının Değişimine Genel Bir Bakış", Süleyman Demirel Üniversitesi Sosyal Bilimler Enstitüsü Dergisi Yıl: 2014/1, Sayı:19, s. 200.

Emevilerle birlikte ve özellikle Abbasi halifesi Mansur'la birlikte önemli gelişmeler gösteren kurumu, İslam dünyasının hemen her yerinde ve her yönetim döneminde belli bir gelişme çizgisinde görmek mümkün olmuştur.[2] Selçuklular döneminde ilk olarak vezir Nizamülmülk tarafından Nişabur'da kurulan darüşşifayı Nizamiye Medresesi ve hastanesi takip etmiş ve sonrasında da birçok şehirde kurulup, geliştirilmişlerdir. Anadolu Selçuklular döneminde bugün Anadolu'nun birçok yerinde rastladığımız darüşşifalardan Kayseri Gevher Nesibe Tıp Medresesi ve Mâristanı, Sivas İzzeddin Keykavus ve Konya darüşşifalarını zikretmek gerekir.[3] Osmanlılar döneminde Selçuklu eserleri çeşitli ilavelerle ve İstanbul, Edirne, Bursa'da örneklerini gördüğümüz gibi yenileri de yapılarak darüşşifalar kullanılmışlardır. İstanbul Fatih, Haseki, Atik Valide, Sultan Ahmed, Bezm-i Âlem darüşşifaları, Bursa Yıldırım, Edirne II. Bayezit darüşşifaları örnek olarak verilebilir.[4]

II. DARÜŞŞİFALARIN YAPILIŞ AMACI VE HEDEF KİTLESİ

Darüşşifaların öncelikle kimsesiz ve muhtaç durumda olan hastalara hizmet vermek maksadıyla, padişah, sultanlar ve diğer devlet erkanı ve eşleri vasıtasıyla kurulduğunu görüyoruz.[5] Kadınların kurduğu şifahanelerin bolca örneklerine rastlamak mümkündür. Buna bir örnek Manisa'daki Ayşe Hafsa Sultan Bîmarhanesi'dir. Ayşe Hafsa Sultan, Yavuz Sultan Selim'in karısı, Kanunî Sultan Süleyman'ın annesidir. Oğlunun sancakbeyliği sırasında Manisa'ya büyük bir külliye kazandırmıştır.[6] Hastanenin bulunduğu

2 Terzioğlu, Arslan, "Bimaristan", DİA, VI, 163 vd.

3 Kelebek, Mustafa, İslam Vakıf Hukuku ve Sivas Darüşşifa Vakfiyesi, İstanbul 2015, s. 88 vd.

4 Şeker, Mehmet, İslâm'da Sosyal Dayanışma Müesseseleri, Ankara 1991, s. 164- 165; Yılmaz, Coşgun/Yılmaz, Necdet, "Osmanlı Hastahane Yönetmelikleri: Vakfiyelerde Osmanlı Dârüşşifâları", Osmanlılarda Sağlık Health in The Ottomans I, Ed. Dr. Coşgun Yılmaz- Dr. Necdet Yılmaz, İstanbul 2006, s.43 vd.

5 Turan, Osman, Selçuklular Tarihi ve Türk-İslam Medeniyeti, 10. Baskı, İstanbul 2008, s. 342 vd.; Ünver, A Süheyl, "Büyük Selçuklu İmparatorluğunda Vakıf Hastanelerin Bir Kısmına Dair", Vakıflar Dergisi, sy. 1, s. 15.

6 Cunbur, Müjgan, "Selçuklu Ve Osmanlı Devirlerinde Kadınların Kurdukları Şifahaneler", Erdem, Mayıs 1987, c. 3, sy, 8, s.344.

şehirden geçen o şehirde yakını olmayan yolcular, kendilerine yakınları vasıtası ile bakım sağlanamayan kimsesiz ve yoksul olanlara ücret almaksızın tedavi ve bakım imkanı sağlanan yerler olarak görülür.

Darüşşifaların temelinde çoğunlukla bir vakıf olduğunu, vakıfların da kuruluş gayeleri arasında hayırda süreklilik (*sadaka-i cariye*) anlayışının bir gereği olarak Allah rızası için kuruldukları söylenebilir.[7] Bu sağlık kuruluşları din, dil ve ırk farkı gözetmeden halka sağlık hizmeti sunmaktaydı. Darüşşifaların mimarilerinin zaman içerisinde bazı farklılıklar olsa bile, hemen hemen birbirine benzer olduğu görülür. Ortası avluya revaklarla açılan ve kenarlarda kubbeli eyvanların gerisinde odalardan müteşekkil yapılar vardır. Burada dikkati çeken husus mimarinin kendi içinde bir bütünlük sağladığı ve tıbbın gerektirdiği fonksiyonlara uygunluk arz etmesidir. Mimarilerde en temel özellik darüşşifaların medrese, imaret, kervansaray, hamam gibi külliyenin diğer bileşenleriyle birlikte düşünülüyor olmasıdır.[8] Darüşşifaların önemli özelliklerinden birisi de ticaret merkezi ve yollarına yakınlık göstermesidir.[9] Bunun da çoğunlukla ticaret amaçlı ve ticari sebeplerle seyahat eden ve kendi bölgesinden uzak düşmüş insanların istifadesinin öncelikler arasında düşünülmüş olabileceğini gösterir.

Darüşşifalarda tedavi kuruluş amacına da uygun olarak ücretsiz yerine getirilirdi.[10] Gelen hasta öncelikle maddi temizliğini sağlamak maksadıyla hamamda yıkanır ve sonrasında hastane kıyafeti verilirdi. Şifahanelerin kendi bütünlüğü içerisinde yakınında veya içinde hamam olduğu gibi, su ve ısıtma sistemi ile ilaç hazırlanmaya müsait eczahaneler de zorunlu unsurlardan sayılırdı. Muayenelerde mümkünse birden çok hekim ve tıp öğrencileri birlikte bulunurlar, günümüz şartlarında çoklu konsültasyon denilen

7 Aykanat, Mehmet, Osmanlı Sosyal Güvenlik Hukuku, Ankara 2016, s. 68, 183.

8 Kazıcı, Ziya, Osmanlıda Vakıf Medeniyeti, İstanbul 2014, s. 200.

9 Dündar, Munis/Emekli, Rabia/Şener, Elif, "Anadolu'daki Tıbbın Doğuşu, Dünyadaki İlk Tıp Okulu Olarak Gevher Nesibe Tıp Medresesi Ve Darüşşifası", Bilimname, XXXIX, 2019/3, s. 84; Ayrıca bkz. Aydın, Erdem, Anadoludaki Ticaret Yolları ve Selçuklu Sağlık Hizmetleri. Yeni Tıp Tarihi Araştırmaları, yıl 1996, sy. 2-3, s. 164-175.

10 Küçükdağ, Yusuf, Konya Alaeddin Darüşşifası, Konya 2008, s. 31; Kemaloğlu, Muhammet, "XI.-XIII. Yüzyıl Türkiye Selçuklu Devletinde Dârüşşifalar", Hikmet Yurdu, Düşünce-Yorum Sosyal Bilimler Araştırma Dergisi, Cilt 7, Sayı 13 (2014): Ocak – Haziran 2014/1, s. 295.

mekanizma böylece yerine getirilmiş olurdu. Öngörülen ilaç ve beslenme rejimine uygun olarak hasta takibe alınırdı.[11]

III. DARÜŞŞİFALARIN İŞLEYİŞİ VE HEKİMLER

Darüşşifaların İslam medeniyeti içerisinde gelişmesinin temelinde, bunların vakıf anlayışının ürünü olmaları yatmaktadır. Medreselerin yanında *darü't-tıp* adı verilen tıpla ilgili eğitim veren kurumlar yer almıştır.[12] Vakıfların tarihi süreç içerinde darüşşifalar dışında da birçok kamu hizmetini yerine getirdiklerini görmekteyiz.[13] Osmanlı'da zirvesine ulaşmış vakıf medeniyeti sayesinde günümüz klasik kamu hizmetlerinin önemli bir kısmının vakıflar aracılığıyla yürütüldüğünü görürüz. Buradaki hizmetlerin halkın üstesinden gelemeyeceği alanlar olduğuna dikkat çekilmiştir. Aynı zamanda devletin yükünü azaltmak veya sosyal paylaşım düşüncesi de etkili olmuştur.[14] Vakıflar insanlık tarihinin sosyal güvenlik ve dayanışma adına oluşturmuş olduğu en ideal kurumdur. Halil İnalcık bu hususu, *"vakıf, toplumun bekası ve refahı için en emin sosyal örgüt görevini üstlenmiştir."* sözleri ile özetlemiştir.[15] Hayri vakıflar içerisinde sağlık vakıflarının daha özel bir yer işgal ettiği müşahede edilir.[16] Genelde vakıflar idari-mali özerkliği ve hukuki şahsiyeti olan kurumlar olarak, yine devletin kamu murakabesine tâbi bir şekilde kamu hizmetlerinin gören, toplumun bu hizmetlerde paydaş olmasını sağlayan ve devletin istihdam yükünü azaltan kurumlardır.[17]

11 Altınbaş, Ayten, "Anadolu Selçukluları ve Osmanlılar'da Tıp ve Darüşşifalar", Hazırlayan Abdullah Kılıç, Selçuklu ve Osmanlı Şifa Abideleri, Şifahaneler, Mebkam Konevi Araştırma Merkezi, İstanbul 2015, s. 41 vd.

12 Küçükdağ, Konya Alaaddin Darüşşifası, s.21.

13 Onar, Sıddık Sami, "Bayındırlık, Yardım, Belediye (Komün), İşleri ve Bu İşlerdeki Rolleri Bakımından Osmanlı Vakıfları", s. 313-333 (Özay, İl Han, Gün Işığında Yönetim, Filiz Kitapevi, İstanbul 2004)", s. 314.

14 Genç, Mehmet, "Klâsik Osmanlı Sosyal-İktisadî Sistemi ve Vakıflar", Vakıflar Dergisi, Aralık 2014, sy. 42, s. 15,16.

15 Kurt, Yılmaz, "Tarihçilerin Kutbu Halil inalcık'ın Gözüyle Vakıf Kurumu", VD, Ankara 2016, sy. 46, s. 189; Kozak, İ., Erol, Bir Sosyal Siyaset Müessesesi Olarak Vakıflar, İstanbul 1985, s. 64.

16 Akman, Ahmet, Eski Vakıflar Hukuku ve İdaresi, Ankara 2019, s. 81.

17 Kozak, İ. Erol, Bir Sosyal Siyaset Müessesesi Olarak Vakıflar, s.64.

Darüşşifaların bulundukları bölgelerde istihdam bakımından diğer vakıf hizmetlerine göre daha önde oldukları görülür.[18]

Darüşşifalar için vakıf kurucusunun hazırlamış olduğu vakfiyelerde, hastanenin işleyiş şekilleri de çoğu zaman kesin ve detaylı kurallar halinde belirlenirdi. Vakfiyeler bu kurumların bir nevi yönetmelikleri mesabesindeydi. Vakfiyeler ilgili dönemdeki sağlık anlayışı, temizlik ve beslenme dahil hizmetin sunuş biçimi, kalitesi, kurumsal kimlik ve teşkilat yapısını, insan kaynağı ve nitelikleri, kadro adetleri ve ücretleri, tıp etiği, vakıf gelirleri dolayısıyla ekonomik imkanların kapsama alanı, hekim hasta ilişkisi, psikolojik yaklaşımlar ile sosyal ve manevi ihtiyaçları yansıtırlar.[19] Vakfiyelerde bu kurumun vâkıfın amacına uygun bir şekilde işletilmesi için gereken gelir miktarı ve bunun ne şekilde sağlanacağı tespit edilirdi. Vakıf hukukunda en temel kurallardan birisinin "*vakfedenin şartları şari'in nassı gibidir.*" kuralı olduğunu da unutmamak gerekir. Müsteğallat adı verilen vakfa gelir getirici unsurların bizzat vakfeden tarafından ve sonrasında da o vakfın yaşamasını, gelişmesini isteyen hayır sahipleri tarafından vakfedildiğini görüyoruz. Mesela Sivas Darüşşifa vakfiyesinde üzüm bağları, değirmen, çiftlik, tahıl ambarı, dükkanlar, bazı köyler, arsa ve tarlalar bu çerçevede hastaneye gelir getirmesi vakfedilmişlerdir. Vakfeden, mütevelli ve nazırlara vakfın gelir getiren bir unsurunu kiraya vermek durumunda kalırlarsa bunun peş peşe üç yıldan fazla olmamasını, zalim, tamahkar, mütecaviz ve hileli işleri olanlara kiraya verilmemesini şart koşmuşlardır. Vakıf şartlarında ayrıca, *"…Vâkıf -I. İzzeddin Keykavus- vakfettiği bütün şeyleri her türlü engelden uzak, bütün*

18 Altınbaş, Ayten, "Anadolu Selçukluları ve Osmanlılar'da Tıp ve Darüşşifalar", Hazırlayan Abdullah Kılıç, Mebkam Konevi Araştırma Merkezi, İstanbul 2015, s. 54-59; Şahin, Kamil, "Konya Kadı Izzeddin Mârıstan-I Atik (Hastahanesi) Ve Sultan Alâddin Keykubat Dârussifâsı, Vakıflar Dergisi, 30 (2007), s. 112 –101-116; Demirel, Ömer, Osmanlı Vakıf Şehir İlişkisine Bir Örnek: Sivas Şehir Hayatında Vakıfların Rolü, Türk Tarih Kurumu, Ankara 2000, s. 134, 153.

19 Yılmaz, Coşgun /Yılmaz, Necdet, "Osmanlı Hastahane Yönetmelikleri: Vakfiyelerde Osmanlı Dârüşşifâları", Osmanlılarda Sağlık Health in The Ottomans I, Ed. Dr. Coşgun Yılmaz- Dr. Necdet Yılmaz, İstanbul 2006, s.42 -41-63; Songur/Saygın, Şifahaneden Hastaneye, s. 206 vd.) Bu meyanda örneğin 1557 tarihli Süleymaniye vakfiyeleri içerisinde darüşşifanın işleyişine dair detaylı bilgilere rastlarız. Şeker, İslâmda Sosyal Dayanışma Müesseseleri, s. 164; Yılmaz, Yasin, "Kanuni Dönemi Sağlık Hizmetleri ve Bunlara Vakıfların Katkısı", 2009 Vakıf Medeniyeti Sağlık Yılı , VGM Yay., s.105.

şartların doğruluğu ile kesin kalıcı olarak vakfetti. Hiçbir sebeple satışı, bağışı, rehin, mirasçılara taksim, temlik, gereksiz yere harcama, başka biri ile değiştirme (istibdal) yapılamaz. Vakıf şartları ebediyyen yürürlükte kalacaktır." Devamında da Allah'a iman eden hiçbir kimsenin bu vakfı eksiltmesi, bozması, değiştirmesi, iptal etmesi ve durdurması helal değildir şartı ilave edilmiştir.[20]

Vakfın gelirlerinin toplanıp vakfın amacına uygun şekilde sarfından vakıf mütevellileri sorumludur. Bazı vakıflarda bulunan nâzırlar da bunların denetimini yaparlardı. Mütevelli vakıfta çalışacak olan görevlilerin seçilmesi ve atanmasını vakfiyede yer verilen ölçülere uygun olarak yerine getirir, hastanenin düzeni ve işletilmesinden sorumlu olurdu. Anadolu Selçuklularında kadın ve erkek hastaların oda ve mekanlarının ayrı olduğu ve de zihinsel engelliler için de ayrı ve demir parmaklıklı bir bölümün yer aldığını görürüz.[21] Bu tür hastalara özellikle psikolojik tedavi metodları uygulanmış, hatta bu husus vakfiyelerde de belirtilmiştir. Anadolu'da standart sayılabilecek mimari ve ölçekte ve bağımsız olarak yapılan darüşşifaların umumiyetle 24 kişi civarında bir kadrosu olduğu görülmektedir. Ücretleri yanında buğday ve pirinç istihkakları da vardır. Darüşşifalarda doğaldır ki, en önemli görev hekime aittir. Hekimlerin yetişmesi ve atanması gibi konularda belli bir hiyerarşik yetkiye sahip "*reisületıbba*" adı verilen sarayda da görev yapan üst görevliler genellikle var olmuştur. Osmanlıda bu isimlendirmenin "*hekimbaşı*" olarak yaygınlık kazandığını görüyoruz.[22]

Konya Darüşşifaları da bu meyanda zikre değer varlıklardır. Konya'da 1113 yılında Sultan Melikşah tarafından bir darüşşifanın yaptırıldığını sonraki yıllarda, 1242 yılında bu darüşşifaya yapılan yeni vakıf kayıtlarını muhtevi vakfiyedeki atıftan anlıyoruz. Konya Darüşşifasının kadrosu ile alakalı olarak arşiv belgelerinde bazı bilgilere rastlanır: Katip, hekim-i evvel,

20 Üçer, Müjgan, "Sivas Darüssıhhası", Hazırlayan Abdullah Kılıç, Şifahaneler, Mebkam Konevi Araştırma Merkezi, İstanbul 2015, s. 114; Kelebek, Sivas Darüşşifa Vakfiyesi, s. 135-149; Kazıcı, Ziya, Osmanlıda Vakıf Medeniyeti, İstanbul 2014, s.196.

21 Turan Osman, Selçuklular Tarihi ve Türk-İslam Medeniyeti, 10. Baskı, İstanbul 2008, s. 346.

22 Akpınar, Cemil, "Hekimbaşı", DİA, c.XVII, s. 160 --160-161-; Osmanlı'da hekimbaşıların listesi için bkz. Sarı, Nil, "Hekimbaşı", DİA, c. XVII, s. 162 --161-164.

hekim-i sani, imam-ı mescid-i darüşşifa, müezzini mescid, bevvab, câbi *(tahsildar)*, mütevelli (Hacı Mehmed), mütevelli-i cedid Hacı Yusuf.[23]

I. Alaeddin Keykubad'ın kurucusu olduğu Konya Alaeddin Darüşşifasına da (1221) Sultan tarafından iki tabip atanmış ve ayrıca zaman içerisinde cerrah, kehhal ve hekim şâkirdi adı verilen sağlık görevlileri ile desteklendiğini görüyoruz.[24] Sivas Darüşşifasında olduğu gibi Konya Alaeddin Darüşşifası için vakfedilmiş birçok gelir getirici vakfı ve bu meyanda Konya ve çevresinde birçok gayrimenkulün müstağallat olarak tahsis edildiğini görmekteyiz. Tahsis edilen vakıf gelirlerinin bir düzen içerisinde harcanması da önem arz eder. Bu maksatla bir vakfiye hazırlanıp, o beldenin kadısına tescil ettirilip, darüşşifadaki resmi işlemlerin tamamı vakfiyedeki şartlar gereğince yerine getirilirdi.[25]

Hekim seçilirken aranan niteliklere sahip olması bakımından birçok şart koşulurdu. Bu dönemde hekimler İstanbul, Bağdat, Şam ve Mısır'a giderek, ilave eğitim aldıklarını görüyoruz. Kaynaklarda bu dönemde şöhret bulmuş birçok hekimin ismi verilir.[26] Bilgili ve ehliyetli olmanın yanı sıra vakfiyelerde *"…birçok önemli tıbbi olaya tanık olmuş, mesleklerinin en ince kural ve ilkelerini fevkalade kavramış, tıp ve hikmetin bütün sır ve inceliklerine vakıf olmuş, gördüğü tıbbi vakalarla bilgilerini geliştirmiş…"* olmak şartları mevcuttur. Vakfiyelerin bu kısımlarında kendini zaman içerisinde geliştirme konusu, üzerinde vurgulanan hususlardan olmuştur. Ayrıca hekimin ahlakı ve hastalara davranışı da önem arz etmektedir. Hekimin nazik, güler yüzlü, hastanın halinden anlayan, herkese en yakın velisi gibi davranan, hastalara candan dost gözüyle bakan, insanlara karşı saygıda kusur etmeyen bir karakterde olması da aranmaktaydı. Vakfiyelerde ayrıca hekim ve görevlilerin günlük mesaisine ve hasta takibine dair de yönlendirmeler bulmak

23 Altınbaş, Ayten, "Konya Darüşşifası", Hazırlayan Abdullah Kılıç, Selçuklu ve Osmanlı Şifa Abideleri, Şifahaneler, Mebkam Konevi Araştırma Merkezi, İstanbul 2015, s. 140-142.

24 Küçükdağ, Konya Alaeddin Darüşşifası, s. 28, 34-35.

25 Küçükdağ, Konya Alaeddin Darüşşifası, s. 33, 34.

26 Altınbaş, Ayten, "Anadolu Selçukluları ve Osmanlılar'da Tıp ve Darüşşifalar", Hazırlayan Abdullah Kılıç, Selçuklu ve Osmanlı Şifa Abideleri, Şifahaneler, İstanbul 2015, s. 24-26; Zorlu, Süleyman Emre, Osmanlı Tıp Hukuku, Ankara 2017, s.35, 38.

mümkündür. Haseki Darüşşifası vakfiyesinde geçen ibareler bu konulara ışık tutmaktadır. " *... Onlara (hastalara) en güzel şekilde hitap eder. Sual ve cevapta onlarla en şefkatli yolu tutar. Zira sarf olunan nice sözler vardır ki, onlar hastanın nezdinde cennet kevserinden zülâl ve selsebilden daha tatlıdır. Hastanın tatlı söze ihtiyacı daha çoktur. Hastalara şefkat ve riayet kanatlarını indirip döşer, onların üzerine inayet ve himaye kemerlerini gerer."*[27] Bu kurallara uymamak görevden alınmayı gerektirdiği gibi, vakfiyelerde *"... bu şartlara uymayan hekimin bu hizmet karşılığında almış olduğu ücret, dünyada kursağında kalsın ve ona haram olsun, ahirette de en şiddetli azaba düçar olsun"* şeklinde önemli maddi ve manevi uyarılar da vardır.

Hekimler dışında sağlık hizmeti ile görevli olarak darüşşifalarda hastabakıcılık görevini yürüten "*kayyum*" adı verilen görevliler ve ilaç hazırlayıcılar da bulunmaktaydı. Bunların şartları da hekimlere benzer şekilde vakfiyelerde düzenlenmiş olduğunu görmekteyiz. Darüşşifaların diğer görevlileri de yapılan işin mahiyeti bakımından fikir vermektedir. Bunlar; Kapıcı (*bevvab*), aşçı (*tabbah*), yemek servisi yapanlar (*kâse-keş*), temizlikçi (*ferraş*), çamaşırcı (*câmeşuy*), hamam görevlileri ve ayrıca muhtaç hastaların kişisel temizlik ve yardımı ile ilgilenen *âbriziler* zikredilebilir. Bunlar gerektiğinde hastalara idrar kabı koyarlardı.

16. Yüzyıldan sonra bulaşıcı hastalık olan bölgeden havası daha temiz bölgelere intikalin cevazıyla ilgili fetvalar verilmiş ve de salgından kaçarak görevini yerine getirmeyen kamu görevlilerine de ta'zir ve azil cezaları verilmiştir.[28] Hatta bu meyanda var olan bazı naslardan mülhem olarak izolasyon ve karantina kuralları ile hasta ve diğer insanların hareketliliğine kısıtlamalar getirilmiştir. 1812 tarihli veba salgınında günlük ölenlerin sayısı nüfusa göre yüksek sayılabilecek şekilde 850-900 arasında cerayan etmiş, hatta bir ara 3 bin rakamını bulmuştur. Bu durumda da temizlik, hıjyen, hastalıklı bölgeden uzak durma ve hastanın izole edilmesi gibi konularda bugünküne benzer tedbirlere başvurulduğu görülmüştür.[29] İslam medeniyeti içinde

27 Songur/Saygın, Şifahaneden Hastaneye, s. 202, 207.

28 Varlık, Nükhet, "Tâun", DİA, c. XXXX, s.177.

29 Beyhan, Mehmet Ali, "1811-1812 İstanbul Veba Salgını, Etkileri ve Alınan Tedbirler", 1. Uluslararası Türk Tıp Tarihi Kongresi, 10. Ulusal Türk Türk Tıp Tarihi Kongresi

geliştirilmiş ve "*sağlıklı yaşam kuralları*" denebilecek altı genel kurala temas etmek bugün içinde bulunulan durumla alakalı da ufuk açıcı mahiyettedir. *Esbâb-ı Sitte-i Zaruriyye* de denilen bu altı temel kuralın temas ettiği konular şu noktalarda odaklanmıştır. 1. Hava ve onunla ilgili konular, 2. Yemek-içmek, 3. Spor, hareket, hareketsizlik, 4. Duyguların sağlığa etkisi, 5. Uyku ve onunla ilgili kurallar, 6. Vücutta kalıp atılamayan maddelerden kurtulmak için yapılacaklar. Ayrıca hekimler hastalığı bedenin kendi savunma mekanizmasını geliştirmeye çalışırlar ve bunun için *tiryak* adı verilen bağışıklık sistemini güçlendirecek ilaçlar hazırlarlardı.[30]

IV. SONUÇ VE DEĞERLENDİRME

Günümüzde yaşanan virüs salgınına İslam ve Türk hukuk tarihi perspektifinden bakıldığında, görüldüğü gibi darüşşifaların önemli fonksiyonlar icra ettiğini görürüz. İslam tarihinde konuya dair nas mesabesinde çeşitli tedbirlerin ön görüldüğünü biliyoruz.[31] Hz. Ömer'e Şam'da veba çıktığı haberi verilince vebanın olduğu yere gitmemiş, kendisine, "*Allah'ın kaderinden mi kaçıyorsun?*" sorusuna Allah'ın kaderinden yine O'nun kaderine sığındığını cevabını vermiştir. (*Buhârî, Ṭıb 30; Müslim, Selâm 98-100*) Salgın olan yere yaklaşmamak ve salgın olan yeri terk etmemek, benzerleri bugün de görülen kurallara çok benzemektedir. Bulaşıcı hastalık olan bölgeden havası daha temiz bölgelere intikal tecviz edildiği gibi, salgından kaçarak görevini yerine getirmeyen kamu görevlilerine ta'zir ve azil cezaları da verilmiştir.

Darüşşifaların kuruluş ve işleyişlerinde vakıf medeniyetinin çok derin izleri görülür. Birçok alanda kamu hizmeti yerine getiren vakıflar,

Bildiri Kitabı, 20-24 Mayıs 2008, Ed. Prof. Ayşegül Demirhan Erdemir, Prof. Dr. Öztan Öncel, Prof. Dr. Yusuf Küçükdağ, Yard. Doç Dr. Berrin Okka, Dr. Sezer Erer, c. II, s. 1032-1033.

30 Altınbaş, Ayten, "Anadolu Selçukluları ve Osmanlılar'da Tıp ve Darüşşifalar", Hazırlayan Abdullah Kılıç, Selçuklu ve Osmanlı Şifa Abideleri, Şifahaneler, Mebkam Konevi Araştırma Merkezi, İstanbul 2015, s. 29, 35; Yılmaz, Coşgun /Yılmaz, Necdet, "Osmanlı Hastahane Yönetmelikleri: Vakfiyelerde Osmanlı Dârüşşifâları", Osmanlılarda Sağlık Health in The Ottomans I, Ed. Dr. Coşgun Yılmaz- Dr. Necdet Yılmaz, İstanbul 2006, s.42.

31 Varlık, Nükhet, "Tâun", DİA, c. XXXX, s. 175.

sağlık alanında özellikle devletin önemli ölçüde yükünü almışlardır. Sürdürülebilirlikleri de vakıf gelirleri ile sağlanmıştır. Vakıf hukukunda kuruluş ana statüsü olan vakfiyelerde vakfın kurucusunun iradesi çok önemli yer tutar. Bu vakfiyelerde özellikle gelir, gider ve harcama usulleri tespit edilmiştir. Darüşşifaların işletilmesi için gereken kaynağın tedariki bakımından han, hamam, ürün veren arazi işletmeleri türündeki gelir getirici müsteğallat ve müsakkafat belirtilir. Sonraki dönemlerde de vakıf kurucusu yahut başkalarının bu amaçla vakıf yoluyla bağış tasarrufunda bulunmaları hep görülmüştür.

Hastanenin düzeni ve işletilmesinden esasen mütevelli sorumlu olup, bu şahıs vakıf kurucusunun güvendiği ve işin ehli bir kimse olmak durumundadır. Mütevelli ayrıca hastalıkların teşhisi ve tedavisi konusunda gereken idari tedbirleri almakla da yükümlüdür. Bunlar yapılmadığında vakfın amacına uygun davranılmış olmaz. Mütevellinin ve diğer görevlilerin azil ve tazminat sorumluluğu ile muhatap olmasını gerektirebilir. Mütevelliyi azilden bağışık tutan şartlar geçerli olmaz. Tevliyet geçerli, şart geçersiz halde görülür.[32] Konunun vakıf darüşşifa ilişkisini ortaya koymak bakımından vakfiyelerin en temel hukuki belgeler olduğunun altı çizilmesi gerekir. Güncel *pandemi* döneminde sağlık alanındaki başarımızın temelinde toplumsal hafızamızdaki vakıf medeniyetimizin izlerini görmek mümkündür.

32 Akman, Ahmet, Eski Vakıflar Hukuku ve İdaresi, s. 196, 198.

KAYNAKÇA

Akman, Ahmet, Eski Vakıflar Hukuku ve İdaresi, Ankara 2019.

Akpınar, Cemil, "Hekimbaşı", DİA, c. XVII, s. 160-161.

Altınbaş, Ayten, "Anadolu Selçukluları ve Osmanlılar'da Tıp ve Darüşşifalar", Hazırlayan Abdullah Kılıç, Selçuklu ve Osmanlı Şifa Abideleri, Şifahaneler, Mebkam Konevi Araştırma Merkezi, İstanbul 2015, s. 21-60.

Altınbaş, Ayten, "Konya Darüşşifası", Hazırlayan Abdullah Kılıç, Selçuklu ve Osmanlı Şifa Abideleri, Şifahaneler, Mebkam Konevi Araştırma Merkezi, İstanbul 2015, s. 137-144.

Aykanat, Mehmet, Osmanlı Sosyal Güvenlik Hukuku, Ankara 2016.

Beyhan, Mehmet Ali, "1811-1812 İstanbul Veba Salgını, Etkileri ve Alınan Tedbirler", 1. Uluslararası Türk Tıp Tarihi Kongresi, 10. Ulusal Türk Türk Tıp Tarihi Kongresi Bildiri Kitabı, 20-24 Mayı 2008, Ed. Prof. Ayşegül Demirhan Erdemir, Prof. Dr. Öztan Öncel, Prof. Dr. Yusuf Küçükdağ, Yard. Doç Dr. Berrin Okka, Dr. Sezer Erer, c.II, s. 1029-1037.

Cunbur, Müjgan, "Selçuklu Ve Osmanlı Devirlerinde Kadınların Kurdukları Şifahaneler", Erdem, Mayıs 1987, c. 3, sy. 8, s. 341-348.

Demirel, Ömer, Osmanlı Vakıf Şehir İlişkisine Bir Örnek: Sivas Şehir Hayatında Vakıfların Rolü, Türk Tarih Kurumu, Ankara 2000.

Dündar, Munis/Emekli, Rabia/Şener, Elif, "Anadolu'daki Tıbbın Doğuşu, Dünyadaki İlk Tıp Okulu Olarak Gevher Nesibe Tıp Medresesi Ve Darüşşifası", Bilimname, XXXIX, 2019/3, s. 79-103.

Erdem, Aydın, "Anadoludaki Ticaret Yolları ve Selçuklu Sağlık Hizmetleri", Yeni Tıp Tarihi Araştırmaları, yıl 1996, sy. 2-3, s. 164-175.

Genç, Mehmet, „Klâsik Osmanlı Sosyal-İktisadî Sistemi ve Vakıflar", Vakıflar Dergisi, Aralık 2014, sy. 42, s. 9-18.

Kazıcı, Ziya, Osmanlıda Vakıf Medeniyeti, İstanbul 2014.

Kelebek, Mustafa, İslam Vakıf Hukuku ve Sivas Darüşşifa Vakfiyesi, İstanbul 2015.

Kemaloğlu, Muhammet, "XI.-XIII. Yüzyıl Türkiye Selçuklu Devletinde Dârüşşifalar", Hikmet Yurdu, Düşünce-Yorum Sosyal Bilimler Araştırma Dergisi, Cilt 7, Sayı 13 (2014): Ocak –Haziran 2014/1, s.289-301.

Kozak, İ., Erol, Bir Sosyal Siyaset Müessesesi Olarak Vakıflar, İstanbul 1985.

Kurt, Yılmaz, „Tarihçilerin Kutbu Halil inalcık'ın Gözüyle Vakıf Kurumu", VD, Ankara 2016, sy. 46, s. 189-193.

Küçükdağ, Yusuf, Konya Alaeddin Darüşşifası, Konya 2008.

Onar, Sıddık Sami, „Bayındırlık, Yardım, Belediye (Komün), İşleri ve Bu İşlerdeki Rolleri Bakımından Osmanlı Vakıfları", s. 313-333 (Özay, İl Han, Gün Işığında Yönetim, Filiz Kitapevi, İstanbul 2004.

Sarı, Nil, "Hekimbaşı", DİA, c. XVII, s. 161-164.

Songur, Haluk/Saygın, Tuba, "Şifahaneden Hastaneye" Sağlık Kuruluşlarının Değişimine Genel Bir Bakış, Süleyman Demirel Üniversitesi Sosyal Bilimler Enstitüsü Dergisi Yıl: 2014/1, Sayı:19, s. 199-212.

Şahin, Kamil, "Konya Kadı Izzeddin Marıstan-I Atik (Hastahanesi) Ve Sultan Alâddin Keykubat Dârussifâsı, Vakıflar Dergisi, 30 (2007), s. 101-116.

Şeker, Mehmet, İslâm'da Sosyal Dayanışma Müesseseleri, Ankara 1991.

Terzioğlu, Arslan, "Bimaristan", DİA, c. VI, s.163-178.

Turan Osman, Selçuklular Tarihi ve Türk-İslam Medeniyeti, 10. Baskı, İstanbul 2008.

Üçer, Müjgan, "Sivas Darüssıhhası", Hazırlayan Abdullah Kılıç, Şifahaneler, Mebkam Konevi Araştırma Merkezi, İstanbul 2015, s. 99-118.

Ünver, A. Süheyl, "Büyük Selçuklu İmparatorluğunda Vakıf Hastanelerin Bir Kısmına Dair", Vakıflar Dergisi, sy. 1, 1938, s. 17-23.

Varlık, Nükhet, "Tâun", DİA, c. XXXX, s.175-177.

Yılmaz, Coşgun /Yılmaz, Necdet, "Osmanlı Hastahane Yönetmelikleri: Vakfiyelerde Osmanlı Dârüşşifâları", Osmanlılarda Sağlık Health in The Ottomans I, Ed. Dr. Coşgun Yılmaz- Dr. Necdet Yılmaz, İstanbul 2006, s. 41-63.

Yılmaz, Yasin, "Kanuni Dönemi Sağlık Hizmetleri ve Bunlara Vakıfların Katkısı", 2009 Vakıf Medeniyeti Sağlık Yılı, VGM Yay., s.100 - 115.

Zorlu, Süleyman Emre, Osmanlı Tıp Hukuku, Ankara 2017.

Rapid Access to Covid-19 Pharmaceuticals Via Compulsory License*

Av. Dr. Mustafa Erdoğan**

Abstract

While the coronavirus disease (COVID-19) pandemic continues, governments and the pharma companies have begun assessing the possibility of developing medical countermeasures such as vaccines, antiviral treatments to improve patient recovery rates and contain the virus's spread. No vaccine to protect against the virus nor have adequate antiviral treatments hitherto been registered for the indication. However it is very hopeful that many research groups around the world have accelerated their respected analysis and studies with governments' and pharma companies' contributions. It is believed that the studies and analysis will have been completed successfully in a very near future then the world will meet with an expected medical countermeasures. Nevertheless some governments will be able to express concern about access to or the affordability of the potential countermeasures.

If an entity already holds a patent on a medical countermeasure, the patent owner is granted the exclusive right for a limited period of time to prevent third parties not having the owner's consent from making, using, offering for sale, or selling the patented invention. These exclusive rights are, at the same time, called as 'the monopoly rights granted by patents'. Therefore as mentioned above some governments fear for not accessing to or affording of the medical countermeasures due to the monopoly rights. Nonetheless the monopoly rights can be pierced by third parties in some circumstances provided as a 'limited exceptions to the exclusive rights' and

* This Paper was presented in English.

** Istanbul Bar Association

as an 'other use without authorization of the right holder'. Hence if a medical countermeasure that could be used to treat the coronavirus disease pandemic is in question, in some circumstances third parties will not be able to be required by the patent holder to allow their selves to use the patent in order to meet supply needs, such unauthorized use is generally referred to as a compulsory license.

Compulsory licensing enables a government or competent authority to license the use of an invention to a third party or government agency without the consent of the patent-holder in order to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent. As mentioned above, according to the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which requires WTO Members to provide a minimum level of IP protection, the law of WTO Members shall use the subject matter of a patent without the authorization of the right holder. Article 31 of the TRIPS Agreement regulates some conditions in order to be granted of compulsory licenses. However applications for these conditions tend third parties to negotiate with the patent owner for voluntary license and payment of the remuneration to the patent owner. In 2001, WTO Members adopted Ministerial Declaration at the WTO Ministerial Conference in Doha to simplify the usage of patented pharmaceuticals without any consent of the patent holder while taking measures to protect public health. Therefore when a national emergency or other circumstances of extreme urgency in question, WTO Members have right to grant compulsory licenses without any negotiations with the patented pharmaceuticals' owners in order to fasten the process. Further the Declaration has also bestowed a right to the Members to determine what constitutes a national emergency and circumstances of extreme urgency.

As mentioned at the beginning the coronavirus diseases pandemic has been spreading all over the world. When the World Health Organization declared coronavirus as a pandemic during mid-March, the pandemic constitutes a national emergency. Therefore compulsory licensing procedure will promote the Members to access to Covid-19 medical countermeasures

by relying on the TRIPS Agreement and its ancillary Declaration. Consequently medical countermeasures for the prevention and treatment of Covid-19 pandemic will become global public goods.

Key Words: Patent law, compulsory license, World Trade Organization (WTO), Agreement on Trade- Related Aspects of Intellectual Property Rights (TRIPS), Doha Declaration, public health, national emergency.

Özet

Coronavirüs salgını (COVID-19) devam ederken, hükümetler ve ilaç şirketleri iyileşenlerin sayısını artırmak ve virüsün yayılmasını kontrol altına almak için aşı, virüs önleyici tedaviler gibi gelişen medikal karşı tedbirlerin ihtimalini değerlendirmeye başladılar. Fakat endikasyon için günümüze kadar ne virüse karşı koruyucu aşı ne de yeterli virüs önleyici tedaviler tescil edilebilmiştir. Fakat şu çok ümit vericidir ki dünya çapında birçok araştırma grupları hükümetlerin ve ilaç şirketlerinin katkılarıyla değerli analiz ve çalışmalarını artırmıştır. Çalışmalar ve analizler çok yakın zamanda başarılı bir şekilde sona erdirileceğine ve dünya beklenilen medikal karşı tedavisine kavuşacağına inanılmaktadır. Ancak bazı hükümetler muhtemel medikal karşı tedavilere ulaşmakta veya satın alınabilirlik konusunda endişe yaşamaktadırlar.

Eğer bir varlık medikal karşı tedavi konusunda patent korumasındaysa, patent sahibinin üçüncü kişilerin kendisinin izni olmadan patentli varlığı kullanma, satılığa çıkarma veya satmalarını önlemek için belirli bir zamanla sınırlı olarak münhasır hakkı bulunmaktadır. Söz konusu münhasır haklar aynı zamanda patent tarafından sağlanan tekel hakkı olarak da ifade edilmektedir. Bu sebeple yukarıda da belirtildiği üzere bazı hükümetler söz konusu tekel haklarından dolayı medikal karşı tedbirlere ulaşma veya satın alma konularında korku yaşamaktadırlar. Fakat münhasır hakların bazı istisnaları ve hak sahibinin rızası olmadan diğer kullanımlar olarak da belirlenen bazı şartlar altında tekel hakları üçüncü kişiler tarafından delinebilmektedir. Bu sebeple eğer coronavirüs hastalığı salgınını tedavi eden bir medikal karşı tedbir söz konusu ise, bazı durumlarda üçüncü kişilerin

ihtiyaçları karşılamak için patent sahibinden kendilerine patentli varlığın kullanımı konusunda izin vermesini istemesi gerekmemektedir, söz konusu yetkisiz kullanım zorunlu lisans olarak ifade edilmektedir.

Zorunlu lisans ile hükümetler veya yetkili otoriteler, üçüncü kişilere veya hükümetlere patent tarafından sağlanan münhasır hakkın kullanımının sonucu olarak ortaya çıkan istismarları (tekel) önlemek için patent sahibinin izni olmadan buluşun kullanımı ile ilgili lisans vermektedir. Yukarıda da belirtildiği üzere, Dünya Ticaret Örgütü (DTÖ)'nün Ticaretle Bağlantılı Fikri Mülkiyet Hakları Anlaşması (TRIPS)'na göre ki bu anlaşma üyelerden asgari düzeyde fikri mülkiyet korumasının düzenlenmesini istemektedir, DTÖ üyelerinin herhangi bir yetkilendirme olmadan patent konusunu kullanabilecektir. Nitekim TRIPS 31. maddesi bazı şartlarla zorunlu lisansın verileceğini düzenlemektedir. Fakat söz konusu maddelere başvuru, üçüncü kişileri patent sahibi ile görüşme ile ihtiyari lisansa ve belirli miktarlarda tazminat ödemeye yönlendirmektedir. 2001 yılında, DTÖ üyeleri Doha'da düzenlenen Bakanlar Konferansında kabul edilen Bakanlık Deklarasyonu patentli ilaçların, kamu sağlığını koruma amaçlı önlemler almak amacıyla patent sahibinin izni olmadan kullanımını kolaylaştırmaktadır. Bu sebeple ulusal acil bir durum veya aciliyet gereken diğer durumların söz konusu olması halinde, DTÖ üye ülkeleri işlemleri hızlandırmak için patentli ilaç sahibi ile herhangi bir görüşme yapmadan zorunlu lisans verebilmektedir. İlave olarak Deklarasyon ayrıca kamu sağlığı veya ulusal acil durumun ne olduğunun tanımlanması konusunda üyelere hak tanımaktadır.

Başlangıçta da belirtildiği üzere coronavirüs hastalığı salgını bütün dünyada yayılmaya devam etmektedir. Dünya Sağlık Örgütü tarafından mart ortalarında salgın olarak kabul edildiğinde, söz konusu salgın ulusal aciliyet gerektiren durum halini almıştır. Bu sebeple zorunlu lisans prosedürü üyelerin TRIPS Anlaşmasına ve bağlantılı Deklarasyona uygun bir şekilde Covid 19 medikal karşı tedbirlerine ulaşmalarını sağlayacaktır. Sonuç olarak Covid-19 salgınını önleyici ve tedavi edici medikal karşı tedbirler, küresel kamu malı haline gelecektir.

Anahtar Kelimeler: Patent hukuku, zorunlu lisans, Dünya Ticaret Örgütü (DTO), Ticaretle Bağlantılı Fikri Mülkiyet Hakları Anlaşması (TRIPS), Doha Deklarasyonu, kamu sağlığı, ulusal aciliyet gerektiren durum.

I. Introduction

"WHO has been assessing this outbreak around the clock and we are deeply concerned both by the alarming levels of spread and severity, and by the alarming levels of inaction." said Tedros Adhanom Ghebreyesus, WHO's director-general. Therefore it is called as pandemic which leads to unnecessary suffering and death on mid-march and announced the official name of the disease as Covid-19. After the announcement of Covid-19, the world unfortunately meet with novel virus that has infected humans and caused respiratory disease that range from common colds to deaths all over the universe. Until the Covid-19 virus was first detected, the most well-known case of a coronavirus epidemic was Severe Acute Respiratory Syndrome (SARS), which spread 26 countries and resulted in more than 8.000 cases and 774 deaths after being identified in China in 2002.[1] However in a few weeks, new coronavirus namely Covid-19 has started to affect Italy (173 cases), Spain (15 cases), France (12 cases), United Kingdom (18 cases) and many other countries while being seen more than 5,000 cases in a single day in China.[2] In order to prevent transmitting of disease, as a primary steps, governments keep their citizens under lock down, shut all schools, restaurants, cafe and bars and non-essential supermarkets down. At the same time some countries such as Turkey has started to delivery free face masks and medical supplies not only to its citizens but also more than 50 countries including Italy, Spain, the United Kingdom, China and the United

1 The World Health Organization, 'Disease Information- SARS (Severe Acute Respiratory Syndrome)' (WHO, No Date) <https://www.who.int/ith/diseases/sars/en/> accessed 12 May 2020

2 Statista, 'Number of coronavirus (COVID-19) deaths in Europe since February 2020 (as of May 8, 2020), by country and date of report' (Statista, 8 May 2020) <https://www.statista.com/statistics/1102288/coronavirus-deaths-development-europe/> accessed 12 May 2020

States.[3] However as Dr Macciochi, a lecturer in immunology at the University of Sussex, stated even all people are locked down for this period, it will not enough for Covid-19 to be over, it will only reduce the spread.[4] The only way to mitigate pandemic risks and decrease disease is vaccine or antiviral treatments.[5]

Recently, there is no vaccine to protect against the virus nor are there effective pharmaceutical treatments registered for the indication. However governments and the pharma companies have begun assessing the possibility of developing medical countermeasures such as vaccines, antiviral treatments to improve patient recovery rates and contain the virus's spread. "*We need to develop a vaccine, we need to produce it and to deploy it in every single corner of the world, and make it available at affordable prices.*" said European Commission president Ursula von der Leyen at the joint press conference with a number of world leaders on 24 April.[6] At the same conference all leaders committed to provide *equitable global access to innovative tools for COVID-19 for all*. However, deficiencies of national health systems, divergent political relationships and benefits, restrictions of importations for embargoed countries may cause lower income

3 Dominic Evans, et al, 'Turkey flies medical aid to coronavirus-stricken U.S.' *Reuters* (Ankara, 28 April 2020) <https://www.reuters.com/article/us-health-coronavirus-turkey-usa/turkey-flies-medical-aid-to-coronavirus-stricken-u-s-idUSKCN22A1C5> accessed 12 May 2020

4 Sophie Gallagher, 'If anyone tells you a date they're using a crystal ball: When can we really expect coronavirus to end?' *Independent* (London, 1 June 2020) <https://www.independent.co.uk/life-style/health-and-families/coronavirus-when-will-it-end-date-outbreak-stop-a9414196.html> accessed 1 June 2020

5 Hunter, Kaitlin, et al, 'CoronaCare for Everyone: A Comprehensive Plan to Rescue Health Care' *Third Way* (London, 6 April 2020) <https://www.thirdway.org/memo/coronacare-for-everyone-a-comprehensive-plan-to-rescue-health-care> accessed 06 May 2020; The Council of Economic Advisors, *Mitigating the Impact of Pandemic Influenza through Vaccine Innovation*, (the Executive Office of the President of the US, 2019) <https://www.whitehouse.gov/wp-content/uploads/2019/09/Mitigating-the-Impact-of-Pandemic-Influenza-through-Vaccine-Innovation.pdf> accessed 3 May 2020

6 European Commission, *Von der Leyen announces Global Response and calls for united world front against coronavirus* (Announcement, 24 April 2020) available <https://ec.europa.eu/commission/presscorner/detail/en/AC_20_749> accessed 12 May 2020

countries to fall behind the rest and more loss of lives in such countries. In addition, patented medical countermeasures grant their owners the exclusive right for a limited period of time to prevent third parties not having the owner's consent from making, using, offering for sale, or selling the patented invention, called as 'the monopoly rights granted by patents', set out in the WTO Agreement on TradeRelated Aspects of Intellectual Property Rights ("TRIPS"). Therefore the legal way for all countries to easy access to registered Covid-19 pharmaceuticals without the monopoly rights granted by patents, production capacity, highly financial demands or reimbursements is worth considered.

The TRIPS Agreement has not kept quiet and responds to the concerns of countries about the obstacles mentioned above while allowing member countries to implement certain limited exceptions to exclusive right granted by patent to authorize use of the patented products without the owner's consent under some specific conditions, a legal way known as a 'compulsory licensing'. However it is worth considering that compulsory licenses are only intended as an option of last resort in extraordinary circumstances.[7] Article 31 of the Agreement proposes a number of conditions for the granting of compulsory licenses, such as the need to demonstrate prior negotiations with the patent owner for a voluntary license, the payment of adequate remuneration to the patent holder, the review of the validity of the authorization by a distinct higher authority or judicial authorities. However, these conditions can be waived only in the event of a "national emergency" or other extremely urgent circumstance. Even if a compulsory license is granted in the event of an emergency, the right holder must be informed as soon as reasonably practice.[8] In order to prevent TRIPS Agreement related to WTO Members from taking measures to protect public health, Declaration on the Trips Agreement and Public Health (The Doha Declaration) has been implemented. The Declaration provides the discretion to national governments in discerning when a crisis reaches the level of

7 Manisha A. Desai, 'Compulsory licensing: Procedural requirements under the TRIPS agreement' [2016] 18 PPL 32

8 TRIPS Agreement 1995, s. 31(f).

national emergency without limitation to certain diseases, thereby allowing the issuance of compulsory licenses.[9]

Yet uncertainties in pharmaceuticals, the Covid-19 pandemic has undoubtedly become a case of extreme urgency. Hence some countries have begun to adopt extraordinary measures to ease the conditions governing the use of compulsory licenses.[10] At the same time WHO Director-General has provided his support for the establishment of open access or licensing on reasonable terms for all countries regarding vaccines and similar countermeasures used against Covid-19.[11] The aim of this paper is to critically analyze justifiable usage of the patented pharmaceuticals by governments or pharma companies without the consent of the owner during the Covid-19 pandemic. In order to this aim, the paper develops as follows: Firstly, it sets out the articles of the TRIPS Agreement related to pharmaceuticals and its patent protection. Secondly, as an exception of patented pharmaceutical's protection, the scope of compulsory licensing system is evaluated by discussing its importance and usage in the past. Importance of the Doha Declaration is also assessed as a sole remedy for countries to issue compulsory licensing during national emergency. Then the role of compulsory in the recent Covid-19 pandemic is discussed in the scope of patent system.

9 Doha Declaration 2001, s. 5(c).

10 Chile has implemented 'Resolution for the Granting of Non-Voluntary Licenses Referred to in Article 51 N. 2 Of Industrial Property Law N. 19.030 to Facilitate Access and Availability of Medicines and Technologies for the Prevention, Treatment and Cure of Coronavirus Covid-19' into its law system. <https://www.keionline.org/chilean-covid-resolution> accessed 13 May 2020; Similarly Israel legislated compulsory licenses related to lopinavir/ ritonavir (brand name Kaletra), which is an HIV medicine being tested, including in combination with other products, for effectiveness in the treatment of Covid-19; Similarly Ecuador has implemented new legislation into article 510 of the Código Ingenios. Luis Gil Abinader, Legislative Committee in Ecuador approves resolution on compulsory licensing of patents relating to the coronavirus, <https://www.keionline.org/32429> accessed 13 May 2020

11 World Health Organization, *WHO Director-General's opening remarks at the media briefing on COVID-19* (6 April 2020) <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---6-april-2020> accessed 13 May 2020.

II. Patent Protection of Pharmaceuticals

The cost of introducing a new drug into the market may amount a company anywhere between $ 300 million to $1billion along with all the associated risks at the developmental stage.[12] However, estimated pandemic vaccine will cost $2 billion to $3.7 billion.[13] Therefore spending high cost of either finding or developing new vaccines and their lower costs of reproduction should provide some protection to owner of new vaccine in order to prevent misuse and unauthorized practice. Otherwise misuse offer pharmaceuticals at lower price to all and pharma companies may come across substantial losses though funding billions dollars as mentioned. Therefore lacking in legal protection, no pharma company will like to risk its pharmaceuticals becoming a public goods without sufficient profit.

In order to provide a legal protection for intellectual properties, especially "*the establishment of a multilateral framework of disciplines for trade in services and for the protection of trade-related intellectual property rights …*", the WTO created a framework whereby nations participating in the Trade- Related Aspects of Intellectual Property Rights ("TRIPS") Agreement.[14] According to the time periods settled in the Agreement, all members of WTO are needed to comply with these standards by implementing into their legislation. Any failure to give these standards effect in their legislation or comply with these standards determined in the Agreement may stand the failed member on trial under the dispute settlement system, which may cause in trade sanctions by the WTO. Unlike other treaties of

12 Chandra Nath Saha, Sanjib Bhattacharya. 'Intellectual property rights: An overview and implications in pharmaceutical industry' [2011] (Apr-Jun), Vol 2 (2) JAPT & R 91.

13 John-Arne Røttingen, et al. 'Estimating the cost of vaccine development against epidemic infectious diseases: a cost minimisation study' [2018] LGH 1392; Jillian Deutsch, 'Coronavirus vaccine could cost more than Europe's willing to pay' *Politico* (22 April 2020) <https://www.politico.eu/article/whos-going-to-pay-the-bill-to-create-a-vaccine/> accessed 15 May 2020.

14 Jacob A. Lewis, 'Compulsory Licensing: Monster or Myth?' [2014] 82(4) KCLR 1055.

its kind, the TRIPS Agreement solely regulates intellectual property protection as applied to WTO members.[15]

The TRIPS Agreement set minimum standards for the shield and enforcement of intellectual property rights, comprising patents, trademarks, copyrights and etc. According to article 27 of the Agreement, member states are required to provide a patent protection "*for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application*". In addition, the Agreement does not bring a limitation for patents by stating that "*patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*"[16] As seen that the provision requires WTO members to provide patent protection not only for pharmaceuticals but also process of manufacture.

Patent protection plays a significant role in preventing unauthorized persons from using the patented process and from making, using, offering for sale, or importing the patented product or a product obtained directly by the patented process. The main reason behind the patent protection of pharmaceuticals is that as mentioned above pharma companies invest millions of dollars to produce a new vaccine or pharmaceuticals so they need to be sure of sufficient precautions to protect their investments.[17] Therefore due to the need for protect new vaccine from unauthorized use or benefit, the companies spent billions for research, development and test apply for the protection of patent. By patent protection for pharmaceuticals, the companies may easily profit their pharmaceuticals by manufacturing and selling them. Hence as an economic result of patent protection, the companies may profit from their innovations in a long period without interference by anyone and recoup their expensive research and development costs in

15 Christopher K. Eppich, 'Patenting Dilemma: Drugs for Profit Versus Drugs for Health' [2002] 43(1) SCLR 296.

16 TRIPS Agreement 1995, s. 27(1).

17 Caroline Manne, 'Pharmaceutical Patent Protection and TRIPS: The Countries that Cried Wolf and Why Defining "National Emergency" Will Save Them From Themselves' [2010] 42 GWILR 354; Lewis (n 14) 1068.

the financially demanding pharmaceutical industry.[18] The economic importance of patent protection of pharmaceuticals is also stated by former WTO Director-General Mike Moore about patent protection of pharmaceuticals that "*a patent system that rewards companies for risking millions on research, anti-AIDS drugs would not exist*".[19]

The need for this level of patent protection for pharmaceuticals is not only providing financial support but also encouraging pharma companies for developing new drugs.[20] Because as mentioned in the Agreement a patent may grant the patent owner a right to exclude others from practicing the process which the owner found or developed. Therefore if no patent protection available, inventions or developments may be kept secret and be unable to go beyond contract between the inventor and the state. The essence of the pharmaceutical patent protection is also stated as "*… , intellectual property rights play a singularly important role in promoting development and availability of new products to treat diseases. Intellectual property rights are essential for turning ideas into candidates, turning candidates into safe and effective products, and for delivering products into the market.*"[21]

All these protections provide the exclusive right the owner of the patented pharmaceuticals. According to article 28 of the TRIPs Agreement, the patent owner is granted the exclusive right for a limited period of time

18 It is asserted that pharmaceutical companies may recover the investment they had made within the first eighteen months of bringing a pharmaceutical to market; Donald W. Light & Rebecca Warburton, 'Demythologizing the High Costs of Pharmaceutical Research' [2011] 6 Biosocieties 34,35.

19 Mike Moore, 'International Herald Tribune- Yes, Drugs for the Poor — and Patents as Well' (22 February 2001) <https://www.wto.org/english/news_e/news01_e/tn_dg_iht_feb2001_e.htm> accessed 16 May 2020.

20 Arnoldo Lacayo, 'Seeking a Balance: International Pharmaceutical Patent Protection, Public Health Crises, and the Emerging Threat of Bio-Terrorism' [2002] 33 2/3 TUMIALR 301.

21 Richard Wilder, 'Market Segmentation: Techniques, Actors and Incentives - The use of Intellectual Property Rights' Presentation at the Workshop on Differential Pricing and Finance of Essential Drugs Hosted by the World Health Organization and World Trade Organization (Apr. 8-11, 2001), <https://www.wto.org/english/tratop_e/trips_e/hosbjor_presentations_e/28wilder_e.pdf> accessed 16 May 2020; Lacayo, 302.

to prevent third parties not having the owner's consent from making, using, offering for sale, or selling the patented invention. These exclusive rights are, at the same time, called as 'the monopoly rights granted by patents'. The term of monopoly or protection provided expires no earlier than twenty years from the date of filing patent application. During the monopoly period, the patent owner of pharmaceutical can manufacture the pharmaceuticals and determine the price without fear of competition. For instance the pharmaceutical is compulsory for an individual to survive and be healthy, the companies usually bear high prices.[22] The monopoly on the patented pharmaceuticals is worth considering for pharma companies in order them to gain adequate safeguards to protect their pharmaceuticals which is invested the millions of dollars required to produce or develop a medicine. Therefore no pharma company invest the amount required to develop and find a new medicine without the monopoly rights granted by patents. Nevertheless in some circumstances, such as public health in question, it is needed to weaken the restrictive effect of exclusive rights or monopoly on pharmaceuticals and provide a balance between the patent owner's interest and those the public in the diffusion of knowledge and access to, and affordability of the pharmaceuticals. Therefore by lessening the effect of monopoly, it becomes pharmaceuticals accessible and low price in a limited term. As compulsory needs for lower income countries to attain pharmaceuticals readily at a low price, the TRIPS Agreement contains several permissible exceptions on the exclusive rights, by allowing states to issue compulsory licenses. During the Covid-19 period, interest in the compulsory licensing of new expected vaccine has been steadily growing regardless of a state's income level.

III. Compulsory Licensing

As a result of the monopoly rights, pharmaceutical companies strictly enforce pharmaceutical patents to charge outrageous prices that low income individual or countries cannot afford. In other words the monopoly

22 A. Hill, et al. 'Minimum costs for producing Hepatitis C direct-acting antivirals for use in large-scale treatment access programs in developing countries' [2014] 58 (7) CID 928.

rights leave the price of pharmaceuticals' prices to pharma companies' own discretion. Therefore under monopoly protection the companies demand their pharmaceuticals to be treated as off-limits private profiteering rather than public good.[23] Nonetheless in some circumstances such as public health concerns or pandemics patent protection or the monopoly granted by patent may be ruled out in order to save lives of the global community. Therefore it may be stated that the monopoly or profit of pharma companies is not subordinate to public health concerns. In other words patent protection does not prevail any lifesaving pharmaceuticals, such as a Covid-19 vaccine.

In addition to the obligations relating to patent protection described above, The TRIPS Agreement contains exceptions to the provisions requiring patent protection, known as flexibilities, in order to reduce the adverse effects of patent protection and safeguard public interest. According to the article 31 of the Agreement, described as "*other use without authorization of the right holder*", the law of a Member of WTO is needed to allow for other use of the subject matter of a patented pharmaceutical without the authorization of the right holder, containing use by the government or third parties. Therefore the Agreement allows member governments to issue compulsory licensing. In such type of licensing governments allow any one or company to produce or develop the patented product without the consent of the patent's owner by reducing the negative effects of patents on price and accessibility. Hence when the governments issue compulsory licenses, the price of pharmaceutical comes down and the availability becomes easier.[24]

Although the TRIPS Agreement allow members to use patented pharmaceuticals without the authorization of the patent owner, some certain procedural conditions determined under article 31 are needed to meet. In

23 Adam Mannan and Alan Story, 'Abolishing the product patent: a step forward for global access to drugs' in J. Cohen, P. Illingworth and U. Schüklenk (eds), *Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing and Pricing* (Pluto Press, 2006) 183.

24 Sara M. Ford, 'Compulsory Licensing Provisions under the TRIPs Agreement: Balancing Pills and Patents' [2000] 15(4) AUILR 946.

other words compulsory licensing has some limitations. First, the proposed user is needed to make efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. However if a member country issues compulsory licensing only in a time of "national emergency" or in cases of "public noncommercial use" in which duration members must notify the patent owner as soon as reasonably practicable. Second, authorization of compulsory licensing must be considered on its individual merits. Third, compulsory licensing is needed to be imposed solely for domestic use and the patent owner must be adequately reimbursed. However the requirement that "efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time" misunderstand by low income countries and applied to compulsory licensing during the HIV or AIDS accepted by high income countries as not to cause national emergency.[25] Pharmaceutical companies and high income countries had begun to be doubt that a considerable number of issuance of compulsory licensing would highly decease the profits and the companies would become more reluctant to develop or find a vaccine.[26] Therefore the scope of the use of compulsory licensing of pharmaceuticals were needed to be limited to highly infectious diseases.

In order to make pharmaceutical products for HIV/AIDS, tuberculosis, malaria, and other infectious diseases accessible and affordable in a short time, in 2001 the Doha Declaration was set forth by implementing some provisions related to more protecting public health, amending the TRIPS Agreement instead. According to the article 1 of the Doha Declaration, the gravity of health problems which affects low income countries such as HIV/AIDS, tuberculosis, malaria and other epidemics is recognized. Article 2 of the Declaration states that the TRIPS Agreement has an importance to resolve worldwide public health diseases. Article 3 provides

25 Lacayo (n 20) 308; Manne (n 17) 360; Lewis (n 14) 1058.

26 Kyung-Bok Son, 'Importance of the intellectual property system in attempting compulsory licensing of pharmaceuticals: a cross-sectional analysis' [2019] 15(42) GH 6.

a balance between intellectual property protection for the development of new pharmaceutical products and the concerns about its effects on prices. Therefore if the fragile point is infringed, in other words, when prohibitive pricing of pharmaceuticals which is the low income countries' concern prevails over intellectual property right protection which is the developed world's and pharma companies demand or vice versa, there will be a chilling effect on research and development of pharmaceuticals.[27] Article 4 of the Declaration affirms that in order to protect public health, the TRIPS Agreement does provide Members to ignore restrictions. In addition ambiguities are needed to be interpreted in a manner of the Members' right to protect public health and to promote access to medicine. According to the Article 5 each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. In addition each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency related to HIV/AIDS, tuberculosis, malaria and other epidemics. Furthermore the article 5 creates a more flexible approach to compulsory licensing method and exhausting the patent rights by demanding all the Agreement to be understood with a view to promoting public health in low income or developing countries.[28] However the freedom provided by Article 5 is qualified as troubling, because it causes exploitation and importation of non-life saving pharmaceuticals.[29] Articles 4 and 5 are deemed as the heart of the victory for the low income countries.[30] Articles 6 and 7 include some provisions about the low income countries' concern to be promoted and encouraged with technology transfer. Nonetheless article 6 has the textual and interpretive ambiguities causing to inconsistent use of compulsory licensing.

27 World Trade Organization, 'Governments share interpretations on TRIPS and public health' (TRIPS Council- 20 June 2001) <https://www.wto.org/english/news_e/news01_e/trips_drugs_010620_e.htm> accessed 20 May 2020; Lacayo (n 20) 315.

28 Sekalala, Sharifah, *Soft Law and Global Health Problems, In Soft Law and Global Health Problems: Lessons from Responses to HIV/AIDS, Malaria and Tuberculosis* (Cambridge University Press, 2017) 136.

29 Ashley E. Sperbeck, 'A Mathematical Solution to the Sine of Madness that is Pharmaceutical Compulsory Licensing Under the TRIPS Agreement and the Doha Declaration' [2019] 23(1) MIPLR 33.

30 Lacayo, (n 20) 316.

As mentioned above, article 31 (f) of the TRIPS Agreement, pharmaceuticals manufactured under compulsory license can be used predominantly in domestic market, not for exported. However paragraph 6 of the Declaration accepted that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. Therefore the instruction the Council for TRIPS to find an expeditious solution to the problem was needed. Subsequent to the Doha Declaration and a following council decision, an amendment to TRIPS was approved, known as article 31bis. Three major waivers are implied in the article. First the member countries are allowed to export generic pharmaceutical products via compulsory license to meet the need of importing countries.[31] Second waiver is that importing countries' obligations on remuneration to the patent holder under compulsory licensing are waived to avoid double payment.[32] In addition the export side is required to be remunerated. In other words the patent holder is still entitled to be indemnified but the article prevents the issue of double payment the patent holder for the same batch of pharmaceuticals that are produced under compulsory license.[33] The third waiver is related to developing and least developed countries. Exporting constraints are waived for developing and least-developed countries to allow them to export within a regional trade agreement, when at least half of the members were categorized as least-developed countries at the time of the decision.[34] This way allows developing countries to make use of economies of scale. All WTO members are entitled to import under this decision, but some developed countries have announced voluntarily that they will not use the system to

31 TRIPS Agreement 1995, s. 31Bis (1); World Trade Organization, 'Fact Sheet: TRIPS and Pharmaceutical Patents Obligations and Exceptions' (2006) <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm> accessed 22 May 2020

32 TRIPS Agreement 1995, s. 31Bis (2); World Trade Organization, 'Fact Sheet: TRIPS and Pharmaceutical Patents Obligations and Exceptions' (2006) <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm> accessed 22 May 2020.

33 Lewis (n 14) 1060.

34 TRIPS Agreement 1995, s. 31Bis (3); World Trade Organization, 'Fact Sheet: TRIPS and Pharmaceutical Patents Obligations and Exceptions' (2006) available <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm> accessed 22 May 2020.

import.[35] On the other hand some countries would only use the system to import in national emergencies or other circumstances of extreme urgency.[36] Several countries have announced to export pharmaceuticals to those countries in need under compulsory license.[37]

In general the new article waives Article 31 (f) of the TRIPS Agreement for low income countries or 'least developed countries' by allowing them to seek pharmaceuticals from other countries via compulsory licensing when they face public health diseases and unable to manufacture pharmaceuticals. Therefore the article 31bis allows least developed countries to issue compulsory licenses to domestic pharmaceutical manufacturers in order them to export medicines from abroad.[38]

It may be stated that the Declaration does not entirely overcome doubts or fears created by the TRIPS Agreement but compel the Members to revise intellectual property laws in compliance with public health or national emergency. In other words, the Declaration gives more power to the state legislatures to issue compulsory licenses where the public health or national emergency concerns overweigh the right of patent holder which is protected by the TRIPS. Therefore low income or developing countries benefit from the national emergency and compulsory licensing provisions by compelling pharmaceutical companies to provide medicines at a considerably low cost.

35 Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom, the US, Czechia, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia.

36 Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates.

37 Norway, Canada, India, and the European Union (EU).

38 Sperbeck (n 29) 37; Lewis (n 14) 1060.

IV. A National Emergency Situation determined under the TRIPS Agreement

"Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency." stated under article 5 (c) of the Doha Declaration. However the Declaration leaves the door open for countries to determine the scope of national emergency which allows to be issued a compulsory licensing. Therefore it is needed to be determined the scope of national emergency in order countries to issue compulsory licensing while countering a disease. Even though the Declaration allows member countries to determine what constitutes a "national emergency" for itself, the countries are under an obligation to define in specific terms what constitutes a "national emergency" in complied with the TRIPS Agreement.

As mentioned above the object and purpose of the TRIPS Agreement is to encourage innovations by granting them intellectual property rights, not exceed to the needs of the public at large, roughly balance between the patent owner's interest and those the public in the diffusion of knowledge and access to, and affordability of the pharmaceuticals. Therefore the definition or scope of national emergency is needed to be complied with the object and purpose of the TRIPS Agreement. According to the WTO subcommittee if the circumstances are predicted to imminently affect a portion of the State's population within a six-month time period, the circumstance will be classified as emergency situation, a circumstance of extreme urgency or a public health crisis.[39] A public health emergency is defined as an occurrence or imminent threat of an illness or health condition, caused by bio terrorism, epidemic or pandemic disease, or (a) novel and highly fatal infectious agent or biological toxin, that poses a substantial risk of a significant number of human facilities or incidents or permanent or long-term disability.[40]

39 Sperbeck (n 29) 42.

40 World Health Organization, 'Humanitarian Health Action: Definitions: Emergencies' <http://www.who.int/hac/about/definitions/en/> accessed 23 May 2020.

It may be inferred from the definitions that national emergency situation may be determined by examining its scope including the ground triggered, temporality and intended target.

The ground triggered to declare national emergency is restricted to the lives, health or safety of the states' populations.[41] Therefore where a situation is endangering the lives or health of the community or there is great concern about imminent death or harm to a significant portion of the nation, a national emergency may exist. Similarly where a disease deprives a majority of people from medicines or sudden pandemic is rapidly spreading, a national emergency deals with these issues in order to be solved. Hence the scope of national emergency is restricted to the situations which is predicted to imminently affect a portion of population.

The time of national emergency maintained is needed to be limited as well. In other words even though the TRIPS does not contain time limit provision, the circumstances of national emergency should be temporary state. Enforcing a time limit on what may be regarded a national emergency is not as easy as in the current disease, but it should not be maintained in perpetuity. The time limit on the circumstances of national emergency is not only beneficial for patent holders or pharmaceutical companies but it also necessary for population of countries afflicted.[42] By placing a time limit on the duration of a national emergency, a country will behave faster to take all compulsory steps and prevent spreading of disease. On the other hand after the expiry date of national emergency, pharma companies sell their medicines high prices than before.

The intended target of national emergency should be a providing public health or facilitate an immediate end to the national emergency. In addition if a country declares national emergency not aiming to access to essential medicine or directly combating the imminent national or public health emergency, it should not be employed. Therefore the aim of declaration

41 Manne (n 17) 371.

42 Manne (n 17) 370.

national emergency should be a seeking of life saving medicines or treatments via compulsory licensing provided under the TRIPS Agreement.

V. Role of Compulsory Licensing in the recent COVID-19 pandemic

The Emergency Committee arranged by the WHO Director-General agreed that the outbreak of novel coronavirus 2019 in the People's Republic of China, with exportations to other countries meets the criteria for a Public Health Emergency of International Concern on Thursday, 30 January 2020.[43] While the coronavirus diseases pandemic has been spreading all over the world, the World Health Organization declared coronavirus as a pandemic during mid-March, the pandemic constitutes a national emergency for compulsory licensing purposes.[44] Concurrently with the WTO, Donald Trump has stated that he was officially declaring a national emergency and also allowed authorities to waive federal regulations and laws, namely "flexibility".[45] The pandemic has spread and still continuing to spread more than 210 countries with 340k deaths and 5m confirmed cases. Therefore countries either declared or are preparing to declare national emergency.

As mentioned above declaration of national emergency is needed to be a final choice for countries interfered in a global health crisis, particularly where that country has not established appropriate legal safeguards

43 World Health Organization, 'Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV)' (30 January 2020) <https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)> accessed 26 May 2020.

44 World Health Organization, 'Coronavirus disease (COVID-19) Pandemic' <https://www.who.int/emergencies/diseases/novel-coronavirus-2019> accessed 4 May 2020.

45 Drew Angerer, 'Trump declares national emergency as coronavirus crisis deepens' *Al Jazeera* (13 Mar 2020) <https://www.aljazeera.com/news/2020/03/trump-declares-national-emergency-coronavirus-crisis-deepens-200313190545345.html> accessed 26 May 2020.

to protect itself from the crisis. In other words if a country has a legal provisions to protect itself from a disease then it may apply to the provisions rather than declaring a national emergency. It should be stated as the first rule that current national emergencies are a final choice for countries. As WTO offered, all the countries impose some precautions, such as maintaining social distance, avoiding crowded place, cleaning hands, keeping their hygiene, using hand sanitizers and face masks, etc.[46] However all the precautions are only protection from the disease rather than containing the virus or treating populations or setting a barrier to stop the spread of the disease. Therefore all countries have no chance not to declare a national emergency in compliance with the TRIPS Agreement. However in order to determine whether the scope of national emergency is complied with the object and purpose of the TRIPS Agreement, it is needed to examine the ground, time and intended target of the declaration.

The ground triggered to declare national emergency is related to the health and lives of the population of countries. As known that the Covid-19 pandemic diseases has affect 5 million people around the world regardless of country, age, gender. In addition the Covid-19 virus still rapidly passes to an average of 5.7 other people according to a mathematical analysis from Los Alamos National Laboratory.[47] Therefore the declaration of national emergency is compulsory for countries because the Covid-19 pandemic has endangered the health and lives of the world's population by causing imminent death or harm.

The circumstances of national emergency should be temporary state, as mentioned above. It should not be maintained in perpetuity. The time of national emergency is not ease to determine before, but countries have restricted the enforcement of national emergency. For instance France have

46 World Health Organization, 'Coronavirus disease (COVID-19) advice for the public' <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public> accessed 26 May 2020.

47 Naomi Kresge, 'Virus May Spread Twice as Fast as Earlier Thought, Study Says' *Bloomberg* (8 April 2020) <https://www.bloomberg.com/news/articles/2020-04-08/virus-may-spread-twice-as-fast-as-earlier-thought-study-says> accessed 26 May 2020.

implemented the provision including "*strictly proportionate to the health risks at stake and appropriate to the circumstances of the time…*".[48] Similarly Japan has extended its national emergency until May 31, in second time.[49] The reaction of Turkey against the national emergency is that Industrial Property Law No: 6769 has been implemented into intellectual property law and declared some novelty. According to the article 129/4 of the Industrial Property Law, the time period in which compulsory licensing is maintain is needed to be determined. Therefore such these examples from the countries show that countries have taken steps strictly appropriate to the circumstances of the time.

The intended target of national emergency is needed to be facilitate an immediate solutions by providing public health and adequate medicine or treatment for their citizens. For instance France has implemented L.3131-15 in the public health code by aiming to fight the health disaster, to take all measures to make available to patients appropriate medicines for the eradication of the health disaster.[50] The USA has implemented "*supplement state and local efforts and capabilities to save lives and to protect property and public health and safety*" in to the Stafford Act regulating to respond to major disasters and emergencies.[51] Turkey has a similar approach that in order to protect public health and national security compulsory licensing is needed to be issued. Therefore any country which intend to threat a disease endangering the lives or health of the community or there is great concern

48 L2234-1 et seq. of the Code of Defence; Francois Pochart, et al. 'Compulsory licenses granted by public authorities: an application in the Covid-19 crisis in France?' *Kluwer Patent* (23 April 2020) <http://patentblog.kluweriplaw.com/2020/04/23/compulsory-licenses-granted-by-public-authorities-an-application-in-the-covid-19-crisis-in-france-part 1/?doing_wp_cron=1589272990.0916969776153564453125#_ftn8> accessed 6 May 2020.

49 Islamuddin Sajid, 'COVID-19: Japan extends national emergency until May 31' Anadolu Agency (Ankara, 4 May 2020) <https://www.aa.com.tr/en/asia-pacific/covid-19-japan-extends-national-emergency-until-may-31/1827937> accessed 26 May 2020.

50 Francois Pochart, et al. (n 48).

51 Charlie Savage, 'Trump Declared an Emergency Over Coronavirus. Here's What It Can Do' *NY Times* (New York, 13 Marc 2020) <https://www.nytimes.com/2020/03/13/us/politics/coronavirus-national-emergency.html> accessed 26 May 2020.

about imminent death or harm to a significant portion may declare national emergency in order to seek a lifesaving pharmaceuticals.

If a member country of WTO faces an imminent public or national health emergency, it may utilize the compulsory licensing framework in order to access pharmaceutical treating the health of population regardless of patent protection and the holder's consent. As mentioned above the Covid-19 pandemic diseases met with the standard for national emergency determined under article 31 of the TRIPS Agreement and the Doha Declaration. Hence the member countries of WTO may issue a compulsory licensing framework in accordance with the TRIPS Agreement and the Doha Declaration.

In order to treat population had a Covid-19 disease, the members may issue compulsory licensing framework without any consent of the patented pharmaceutical's owner. However there is still no vaccine to protect against the virus nor are there effective pharmaceutical treatments registered for the indication. When a pharmaceutical treating Covid-19 diseases of public will be founded, the member countries may be able to access the pharmaceutical without any consent of the holder or negations with the holder.

In order for compulsory licensing framework established by the member countries to comply with the TRIPS Agreement and the Doha Declaration, the countries may satisfy the requirements of compulsory licensing directly or indirectly regulated under the TRIPS Agreement and the Doha Declaration. As mentioned above according to the article 31 of the TRIPS Agreement, the member countries are allowed for use of the subject matter of a patented pharmaceutical without the authorization of the right holder by issuing compulsory licensing. Even though the proposed user is needed to make efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time, during the Covid-19 disease a member country issuing compulsory licensing must notify the patent owner as soon as reasonably practicable.

As mentioned above the authorization of compulsory licensing for Covid-19 pandemic disease must be considered on its individual merits. In other words each reason for issuing a compulsory licensing is needed to subject to independent review. Directly targeting the imminent national or public health emergency appeared after the disease is needed to be the merit of compulsory licensing. Otherwise the issuing of compulsory licensing other than Covid-19 disease may make a country which intend to access the Covid-19 pharmaceutical responsible to reimburse in the dispute settlement mechanism heard in the WTO.

Although the member countries are allowed to access life-saving pharmaceuticals during national emergency without the consent of patent holder, the patent holder is protected in order to balance between the patent owner's interest and those the public in the diffusion of knowledge and access to, and affordability of the pharmaceuticals by being adequately reimbursed. In other words low income or developing countries have allowed to access the needed pharmaceuticals for diseases without the consent of the patent owner, it remains steadfast in the requirement of assuring payment of adequate compensation to patent holders. However a compensation is needed to be adequate for pharmaceuticals. For instance adding reimbursement of royalty fees to the price of the generic drug may actually increase the price of the generic drug to a level nearly equivalent to that of the original brand-name patented drug in Thailand during 1999-2000.[52] Therefore as mentioned in the Agreement the patent owner of the pharmaceutical manufactured to treat Covid-19 disease or stop spreading reimbursed adequately.

As a necessity for compulsory licensing determined under the TRIPS Agreement, the pharmaceutical or treatment is needed to aim at combating the Covid-19 disease. In other words the pharmaceutical or treatment intended to be accessed via issuing compulsory licensing should aim directly targeting the imminent national emergency, namely the Covid-19 pandemic disease. Therefore if a medicine improves patient recovery rates or

52 Eppich, (n 15) 306.

contains the virus's spread or reduces the severity of the disease of Covid-19, it is needed to be the pharmaceutical which is accessed by the members via compulsory licensing. However if any member country seek a pharmaceutical which is not directly targeting to combat the Covid-19 disease, the country would not to exploit the compulsory licensing framework.

As mentioned in the Doha Declaration the issuing of compulsory licensing is needed to be imposed solely for domestic use. However according to the paragraph 3 of the article 31bis, the member countries are allowed to export generic pharmaceutical products via compulsory license to meet the need of importing countries. Therefore, during the Covid-19 disease, if a member country has insufficient or no manufacturing capacities in the pharmaceutical sector, any other member country has a chance to export the needed pharmaceutical for the disease by receiving reimbursement from the imported country.

The compulsory licensing issued for the access pharmaceuticals treating recent Covid-19 pandemic disease also needs time restriction. In other words the access to medicines via the compulsory licensing is needed to be in specific time period, not for continual state. Therefore all members needed to use compulsory licensing should specify the time period when the country access the Covid-19 pharmaceutical by either importing or manufacturing a generic. Upon the expiration of specified time, the country is able to demonstrate a continuing need for the compulsory license to obtain access to pharmaceuticals.

All these criteria discussed above provides a standard for countries not to undermine the intellectual property regime while accessing the needed pharmaceutical without consent of the holder. If a member country adhere the standard, the situation truly calls for the issuance of an immediate compulsory license. Therefore during the Covid-19 disease, pharmaceutical companies may be allowed to produce or develop the patented product without the consent of the patent's owner by reducing the negative effects of patents on price and accessibility, so via compulsory licensing the price of pharmaceutical will come down and the availability become easier.

Although no recent pharmaceutical to protect against the Covid-19 disease nor are effective medical treatment for the indication have been developed or registered, some giant leaps from pharma companies and patent holders warm the cockles of the world's heart. In other words the compulsory licensing system as discussed above has been regulated much as to reduce the negative effects of the monopoly rights granted by patents on price and accessibility, some concrete steps taken by pharmaceutical companies and states make the Covid-19 pharmaceutical accessible and affordable. For instance, AbbVie, the American pharma company, has declared that the company waives any restriction on the Medicine Patent Pool licensees that would prevent generic companies from supplying *lopinavir/ritonavir* (*Kaletra* HIV pill) anywhere in the world for any purpose, especially Covid-19.[53] Therefore the company will no longer enforce patent rights related to *lopinavir/ritonavir* anywhere in the world. In addition it also meant that the monopoly or patent protection on is lifted worldwide so companies around the world may supply the pharmaceutical or manufacture its generic supply of the treatment for Covid-19 disease. The similar approach has been expected from US company Gilead against the monopoly of patented pharmaceuticals during the Covid-19 outbreak. *Remdesivir*, an antiviral drug experimented to treat COVID-19 has registered and first developed by US company Gilead. When the company applied to US regulators for "orphan status", which grant seven years of market exclusivity, for remdesivir, the company became the targeted of public. However after a public reaction, Gilead rescinded the application for orphan status.[54]

In some circumstances such as lacking enough pharmaceuticals for a disease it may make countries vulnerable against the disease, though the TRIPS Agreement with the amended version and Doha Declaration has simplified pharmaceuticals to access or afford by manufacturing or

53 Ellen't Hoen, 'Covid-19 and the comeback of compulsory licensing' (Medicine and Law Policy, 23 Marc 2020) <https://medicineslawandpolicy.org/2020/03/covid-19-and-the-come-back-of-compulsory-licensing/> accessed 27 May 2020.

54 Enrico Bonadio and Andrea Baldini, 'Drug companies should drop their patents and collaborate to fight coronavirus' (Politics and Law- University of London, 3 April 2020) <https://www.city.ac.uk/news/2020/april/drug-companies-should-drop-their-patents-and-collaborate-to-fight-coronavirus> accessed 27 May 2020.

importing, current the Covid-19 disease pandemic has also infected more than millions who needs some special treatment or pharmaceutical or being cured or stopping to disseminate to others. In case of lacking enough pharmaceutical may case unexpected and undesirable consequences. Therefore during the Covid-19 pandemic, countries regardless of low or high income are needed to promote to produce generic pharmaceuticals, much in the way India has been manufacturing since 2006, in order to access adequate number of pharmaceuticals in a reduced price. For instance Indian generic pharmaceutical company Natco has made generic medicine for an anticancer drug and manufactured adequate number of pharmaceuticals for its citizens in a 75% cheaper price than the original, namely Sorafenib.[55] Therefore, as seen that increased pharmaceutical production will allow more individuals to be treated by manufacturing generic pharmaceuticals against the Covid-19 pandemic. Hence generic manufacturing of pharmaceutical for the Covid-19 disease may be deemed the ragged edge of the scope of compulsory licensing providing a balance between the patent owner's interest and those the public in the diffusion of knowledge and access to, and affordability of the Covid-19 pharmaceuticals. However the generic pharmaceuticals for the Covid-19 pandemic would provide not only for developing nations but also developed countries with multiple sources for importation under the Paragraph 6 exception.

55 Ibid.

VI. Conclusion

When the World Health Organization declared coronavirus as a pandemic during mid-March, the pandemic constitutes a national emergency and the pharma companies have begun assessing the possibility of developing medical countermeasures such as vaccines, antiviral treatments to improve patient recovery rates and contain the virus's spread. The novel vaccine both treating the disease and immunizing people against the Covid-19 will cost approximately 3.5b dollars, so the vaccine will be expensive for humanity. In addition the vaccine will be under patent protection which provides the patent owner the exclusive right for a limited period of time to prevent third parties not having the owner's consent from making, using, offering for sale, or selling the patented invention.

National intellectual property policies are needed to be flexible to anticipate social and urgent health circumstances. This approach is considered in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In complied with the TRIPS Agreement, WTO members are allowed to use of a patented invention without the authorization of the patent holder by issuing compulsory license which required from the members to negotiate with the patent owner for voluntary license and payment of the remuneration to the patent owner. However in the event of a national emergency, the WTO member may utilize patented invention by only notifying the patent holder, being waived other requirements.

In order to make pharmaceutical products for HIV/AIDS, tuberculosis, malaria, and other infectious diseases accessible and affordable in a short time, in 2001 the Doha Declaration was set forth by implementing some provisions related to more protecting public health, amending the TRIPS Agreement instead. Subsequent to the Doha Declaration and a following council decision, an amendment to TRIPS was approved, known as article 31bis. After the amendment, the member countries are allowed to export generic pharmaceutical products via compulsory license to meet the need of importing countries.

Public interest would constitute a justifiable motivation for a compulsory license for using patented inventions relating to the treatment and the diagnosis of COVID-19 provided that the patentees do not make such inventions sufficiently available to the market. Therefor countries may be allowed to utilize life-saving pharmaceuticals without the consent of medicine's owner during the Covid-19 term as national emergency. However following due process and maintaining the proportionate needs are the main obligation on countries issuing compulsory licensing to access to pharmaceuticals. Therefore countries issuing compulsory licensing are expected to balance between the patent owner's interest and those the public in the diffusion of knowledge and access to, and affordability of the pharmaceuticals. On the other hand during Covid-19 term, even though the compulsory licensing system has provide a key to countries to access pharmaceuticals, the collaboration with pharma companies are also urgent need for countries and other medicine companies to waive the exclusive rights on some basic medicines. In addition another way to ease pharmaceutical companies rather than the companies had exclusive rights is to promote generic pharmaceuticals which allow more individuals to be treated in a short time and a reduced price.

As a consequence compulsory licensing procedure will promote the Members to access to Covid-19 medical countermeasures by relying on the TRIPS Agreement and its ancillary Declaration in a short time. All the situations living today medical countermeasures for the prevention and treatment of Covid-19 pandemic will become global public goods.

BIBLIOGRAPHY

Angerer, D. 'Trump declares national emergency as coronavirus crisis deepens' Al Jazeera (13 Mar 2020) <https://www.aljazeera.com/news/2020/03/trump-declares-national-emergency-coronavirus-crisis-deepens-200313190545345.html>

Bonadio E. and Andrea Baldini, 'Drug companies should drop their patents and collaborate to fight coronavirus' (Politics and Law- University of London, 3 April 2020) <https://www.city.ac.uk/news/2020/april/drug-companies-should-drop-their-patents-and-collaborate-to-fight-coronavirus>

Desai, M. A. 'Compulsory licensing: Procedural requirements under the TRIPS agreement' [2016] 18 Pharmaceuticals Policy and Law 31-44

Deutsch, J. 'Coronavirus vaccine could cost more than Europe's willing to pay' Politico (22 April 2020) <https://www.politico.eu/article/whos-going-to-pay-the-bill-to-create-a-vaccine/>

Eppich, C. K. 'Patenting Dilemma: Drugs for Profit Versus Drugs for Health' [2002] 43(1) Santa Clara Law Review 289-318

European Commission, Von der Leyen announces Global Response and calls for united world front against coronavirus (Announcement, 24 April 2020) available <https://ec.europa.eu/commission/presscorner/detail/en/AC_20_749>

Evans, D. et al, 'Turkey flies medical aid to coronavirus-stricken U.S.' Reuters (Ankara, 28 April 2020) <https://www.reuters.com/article/us-health-coronavirus-turkey-usa/turkey-flies-medical-aid-to-coronavirus-stricken-u-s-idUSKCN22A1C5>

Ford, S. M. 'Compulsory Licensing Provisions under the TRIPs Agreement: Balancing Pills and Patents' [2000] 15(4) American University International Law Review 941-974

Gallagher, S. 'If anyone tells you a date they're using a crystal ball: When can we really expect coronavirus to end?' Independent (London, 1 June 2020) <https://www.independent.co.uk/life-style/health-and-families/coronavirus-when-will-it-end-date-outbreak-stop-a9414196.html>

Hill, A., et al. 'Minimum costs for producing Hepatitis C direct-acting antivirals for use in large-scale treatment access programs in developing countries' [2014] 58 (7) Clinical Infectious Diseases 928-936

Hoen, E. 'Covid-19 and the comeback of compulsory licensing' (Medicine and Law Policy, 23 Marc 2020) <https://medicineslawandpolicy.org/2020/03/covid-19-and-the-come-back-of-compulsory-licensing/>

Kaitlin, H. et al, 'CoronaCare for Everyone: A Comprehensive Plan to Rescue Health Care' Third Way (London, 6 April 2020) <https://www.thirdway.org/memo/coronacare-for-everyone-a-comprehensive-plan-to-rescue-health-care>

Kresge, N. 'Virus May Spread Twice as Fast as Earlier Thought, Study Says' Bloomberg (8 April 2020) <https://www.bloomberg.com/news/articles/2020-04-08/virus-may-spread-twice-as-fast-as-earlier-thought-study-says>

Lacayo, A. 'Seeking a Balance: International Pharmaceutical Patent Protection, Public Health Crises, and the Emerging Threat of Bio-Terrorism' [2002] 33 2/3 The University of Miami Inter-American Law Review 295-321

Lewis, J. A. 'Compulsory Licensing: Monster or Myth?' [2014] 82(4) University of Missouri-Kansas City, School of Law Review 1055-1075

Light D. W. and Rebecca Warburton, 'Demythologizing the High Costs of Pharmaceutical Research' [2011] 6 Biosocieties 34-50

Mannan A. and Alan Story, 'Abolishing the product patent: a step forward for global access to drugs' in J. Cohen, P. Illingworth and U. Schüklenk (eds), *Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing and Pricing* (Pluto Press, 2006)

Manne, C. 'Pharmaceutical Patent Protection and TRIPS: The Countries that Cried Wolf and Why Defining "National Emergency" Will Save Them From Themselves' [2010] 42 George Washington International Law Review 349-379

Moore, M. 'International Herald Tribune- Yes, Drugs for the Poor — and Patents as Well' (22 February 2001) <https://www.wto.org/english/news_e/news01_e/tn_dg_iht_feb2001_e.htm>

Pochart, F. et al. 'Compulsory licenses granted by public authorities: an application in the Covid-19 crisis in France?' Kluwer Patent (23 April 2020) <http://patentblog.kluweriplaw.com/2020/04/23/compulsory-licenses-granted-by-public-authorities-an-application-in-the-covid-19-crisis-in-france-part 1/?doing_wp_cron=1589272990.0916969776153564453125#_ftn8>

Røttingen, J. et al. 'Estimating the cost of vaccine development against epidemic infectious diseases: a cost minimisation study' [2018] LGH Lancet Glob Health 1386-1396

Saha, C. N. and Sanjib Bhattacharya. 'Intellectual property rights: An overview and implications in pharmaceutical industry' [2011] (Apr-Jun), Vol 2 (2) Journal of Advanced Pharmaceutical Technology & Research 88-93

Sajid, I. 'COVID-19: Japan extends national emergency until May 31' Anadolu Agency (Ankara, 4 May 2020) <https://www.aa.com.tr/en/asia-pacific/covid-19-japan-extends-national-emergency-until-may-31/1827937>

Savage, C. 'Trump Declared an Emergency Over Coronavirus. Here's What It Can Do' NY Times (New York, 13 Marc 2020) <https://www.nytimes.com/2020/03/13/us/politics/coronavirus-national-emergency.html>

Sharifah, S. *Soft Law and Global Health Problems, In Soft Law and Global Health Problems: Lessons from Responses to HIV/AIDS, Malaria and Tuberculosis* (Cambridge University Press, 2017)

Son, K. B. 'Importance of the intellectual property system in attempting compulsory licensing of pharmaceuticals: a cross-sectional analysis' [2019] 15(42) Global Health 1-8

Sperbeck, E. A. 'A Mathematical Solution to the Sine of Madness that is Pharmaceutical Compulsory Licensing Under the TRIPS Agreement and the Doha Declaration' [2019] 23(1) Marquette Intellectual Property Law Review 22-55

Statista, 'Number of coronavirus (COVID-19) deaths in Europe since February 2020 (as of May 8, 2020), by country and date of report' (Statista, 8 May 2020) <https://www.statista.com/statistics/1102288/coronavirus-deaths-development-europe/>

The Council of Economic Advisors, Mitigating the Impact of Pandemic Influenza through Vaccine Innovation, (the Executive Office of the President of the US, 2019) <https://www.whitehouse.gov/wp-content/uploads/2019/09/Mitigating-the-Impact-of-Pandemic-Influenza-through-Vaccine-Innovation.pdf>

Wilder, R. 'Market Segmentation: Techniques, Actors and Incentives - The use of Intellectual Property Rights' Presentation at the Workshop on Differential Pricing and Finance of Essential Drugs Hosted by the World Health Organization and World Trade Organization (Apr. 8-11, 2001), <https://www.wto.org/english/tratop_e/trips_e/hosbjor_presentations_e/28wilder_e.pdf>

World Health Organization, 'Coronavirus disease (COVID-19) advice for the public' <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public>

World Health Organization, 'Coronavirus disease (COVID-19) Pandemic' <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>

World Health Organization, 'Disease Information- SARS (Severe Acute Respiratory Syndrome)' (WHO, No Date) <https://www.who.int/ith/diseases/sars/en/>

World Health Organization, 'Humanitarian Health Action: Definitions: Emergencies' <http://www.who.int/hac/about/definitions/en/>

World Health Organization, 'Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak

of novel coronavirus (2019-nCoV)' (30 January 2020) <https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)>

World Health Organization, WHO Director-General's opening remarks at the media briefing on COVID-19 (6 April 2020) <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---6-april-2020> accessed 13 May 2020 World Trade Organization, 'Governments share interpretations on TRIPS and public health' (TRIPS Council- 20 June 2001) <https://www.wto.org/english/news_e/news01_e/trips_drugs_010620_e.htm>

World Trade Organization, 'Fact Sheet: TRIPS and Pharmaceutical Patents Obligations and Exceptions' (2006) <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm>

World Trade Organization, 'Fact Sheet: TRIPS and Pharmaceutical Patents Obligations and Exceptions' (2006) <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm>

World Trade Organization, 'Fact Sheet: TRIPS and Pharmaceutical Patents Obligations and Exceptions' (2006) available <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm>