POWERHOUSE POINTS

A Quarterly Litigation Update

Summer 2021

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Freeborn

Illinois Supreme Court Holds Insurance Company Owed Duty to Defend Insured against Class-Action Lawsuit alleging Violations of the Biometric Information Privacy Act

Matthew T. Connelly, Attorney

Recently, in *West Bend Mutual Insurance Company v. Krishna Schaumburg Tan, Inc.,* 2021 IL 125978, the Illinois Supreme Court held that an insurance company owed a duty to defend its insured, a tanning salon, against a class-action lawsuit alleging the salon violated the Biometric Information Privacy Act ("BIPA"). The Illinois Supreme Court found that the duty to defend was owed pursuant to the language of the insured's business owner's policy, which provided coverage for lawsuits alleging "personal injury" or "advertising injury." This case will likely have significant ramifications for the insurance industry due to the growing prevalence of BIPA class-action lawsuits and the substantial settlement amounts that have resulted from such suits.

The Illinois Biometric Privacy Act

BIPA is a relatively new statute that was enacted in Illinois in 2008. *See* 740 ILCS 14/1. The statute regulates how private entities may collect and obtain people's biometric identifiers or biometric information (such as fingerprints, voiceprints, facial scans, etc.), as well as bars selling or otherwise profiting from individual's biometric identifiers or biometric information. *See* 740 ILCS 14/15. Critically, the statute provides for a private right of action by any person aggrieved by a violation of BIPA, further providing that a prevailing party may recover damages between $1,000 to $5,000 for each violation of BIPA, as well as attorney's fees. *See* 740 ILCS 14/20.

Since BIPA's enactment, there has been an increasing amount of class-action lawsuits alleging violations of BIPA, with over 800 BIPA class-actions filed in just the past few years.[1] Moreover, some of these cases have recently resulted in substantial settlement amounts. For example, earlier this year the United States District Court for the Northern District of California entered final approval of a $650 million settlement against Facebook in a landmark class-action case alleging violations of BIPA.[2]

Powerhouse Points

- Insurance policy's coverage for "personal injury" and "advertising injury" was sufficient to trigger duty to defend the insured against a class-action lawsuit alleging violations of the Biometric Information Privacy Act.
- Insurance company could not avoid duty to defend under the policy's "violation of statute" exclusion.
- Due to the rising number of Biometric Information Privacy Act class-action lawsuits, insurers and insureds should be aware of this decision and its impact on general liability policies.

1 Kwabena Appenteng & Andrew Gray *Illinois Legislature Considers a Bill Designed to Slow the Flood of Biometric Privacy Class Actions,* JDsupra (March 26, 2021), https://www.jdsupra.com/legalnews/illinois-legislature-considers-a-bill-8258761/.

2 See Order re Final Approval, Attorney's Fees and Costs, and Incentive Awards, ECF No. 537, *In re Facebook Biometric Information Privacy Litigation,* 2021 WL 757025 (N.D. Cal. 2021) (Case No. 1:15-cv-03747) .

Further, this year, a Cook County judge approved a $25 million settlement in a BIPA class-action lawsuit against ADP.[3] In addition, the United States District Court for the Northern District of Illinois is currently considering approval of a proposed $92 million class-action settlement against Tiktok, Inc. for allegedly violating BIPA.[4]

While the Illinois legislature introduced a bill earlier this year to impose new limits on BIPA, the bill was referred to the Rules Committee and was not called for a vote prior to end of the spring general session.[5] As a result, for the foreseeable future it is likely that courts will continue to see a surge in new BIPA class-action lawsuits.

West Bend Mutual Insurance Company v. Krishna Schaumburg Tan, Inc.

This case involved an insured, Krishna Schaumburg Tan, Inc. ("Insured"), which was a franchisee of L.A. Tan. The Insured had a business owner's policy from West Bend Mutual Insurance Company ("Insurer") which provided "Business Liability" coverage for lawsuits involving "Personal Injury" or "Advertising Injury."

A class-action lawsuit was filed against the Insured, which alleged that the tanning salon violated BIPA by requiring its customers to provide their fingerprints, and then disclosing the customer's fingerprints to an out-of-state vendor, SunLync. The salon tendered defense of the class-action lawsuit to the Insured pursuant to the language of the business owner's policy.

The Business Owner's Policy

The business owner's policy at issue provided coverage for lawsuits alleging a "Personal Injury," defined as an "injury, other than 'bodily injury,' arising out of one or more of the following offenses: . . . Oral or written ***publication*** of material that violates a person's right of privacy." *W. Bend Mut. Ins. Co.,* 2021 IL 125978, ¶ 8 (emphasis added). Similarly, the policy provided coverage for lawsuits alleging an "Advertising Injury," defined as an "injury arising out of one or more of the following offenses: . . . Oral or written ***publication*** of material that violates a person's right of privacy." Id. (emphasis added).

In addition, the policy contained a "violation of statutes" exclusion that stated:

"This insurance does not apply to:

DISTRIBUTION OF MATERIAL IN VIOLATION OF STATUTES

'Bodily injury', 'property damage', 'personal injury' or 'advertising injury' arising directly or indirectly out of any action or omission that violates or is alleged to violate:

(1) The Telephone Consumer Protection Act (TCPA) [(47 U.S.C. § 227 (2018))], including any amendment of or addition to such law; or

(2) The CAN-SPAM Act of 2003 [(15 U.S.C. § 7701 (Supp. III 2004))], including any amendment of or addition to such law; or

(3) Any statute, ordinance or regulation, other than the TCPA or CAN-SPAM Act of 2003, that prohibits or limits the sending, transmitting, communicating or distribution of material or information." Id. at ¶ 9.

Defense Coverage Litigation

The Insurer rejected coverage for the Insured's defense costs in the underlying BIPA class-action suit and filed a declaratory judgment action denying any duty to defend on the grounds that there was no "personal injury" or "advertising injury" alleged in the class-action. Specifically, the Insurer argued that there was no "publication" of information that violated any person's right to privacy that would trigger a duty to defend under the business owner's policy because the Insured only sent its customer's biometric information to a single third-party vendor rather than to the public at large. Further, the Insurer argued that the violation of statutes exclusion in the policy barred any coverage in this matter. In response, the Insured filed a counterclaim arguing that the Insurer owed a duty to defend under the plain language of the policy.

Following cross-motions for summary judgment, the trial court ruled in the Insured's favor. The trial court held that the term "publication" in the business owner's policy "simply means the dissemination of information," which can be to a single person rather than to the public at large. The trial court also found that the violation of statutes exclusion in the policy was inapplicable because, based on the specific statutes mentioned in the exclusion, the exclusion was only intended to relate to violations of statutes regulating communications, whereas BIPA regulates the collection and use of biometric identifiers and biometric information.

3 Jonathan Bilyk, *Judge OKs $25M deal to end IL biometrics class actions vs ADP over worker fingerprint scans*, CookCountyRecord (March 1, 2021), https://cookcountyrecord.com/stories/574995201-judge-oks-25m-deal-to-end-il-biometrics-class-actions-vs-adp-over-worker-fingerprint-scans.

4 See Pl's Mot. for Settlement, ECF No. 122, *In re: Tiktoc, Inc., Consumer Privacy Litigation*, MDL No. 2948, (N.D. IL, Feb. 25, 2021), (Case No. 1:20-cv-4699); Minute Entry, ECF No. 158, *In re: Tiktoc, Inc., Consumer Privacy Litigation,* MDL No. 2948, (N.D. IL, Apr. 19, 2021) (Case No. 1:20-cv-4699).

5 Illinois General Assembly, https://www.ilga.gov/legislation/BillStatus.asp?DocNum=559&GAID=16&DocTypeID=HB&LegId=128636&SessionID=110&GA=102 (last visited June 21, 2021).

The Insurer appealed, and the appellate court affirmed the trial court's ruling on the same basis. As a result, the Insurer appealed to the Illinois Supreme Court.

Illinois Supreme Court's Analysis

In determining whether the Insurer's duty to defend was triggered by the BIPA class-action lawsuit, the Illinois Supreme Court first analyzed whether the Insured's alleged sharing of its customer's biometric information with the third-party vendor constituted as a "publication" under the insurance policy. Because "publication" was not defined in the policy, the Illinois Supreme Court analyzed dictionary definitions to define the term, as well as case law and the Restatement (Second) of Torts. Through this analysis, the Illinois Supreme Court found that "the term 'publication' has at least two definitions and means both the communication of information to a single party and the communication of information to the public at large." *Id.* at ¶ 43. Further, the Illinois Supreme Court found that if there is an ambiguous term in an insurance policy, then the term should be construed broadly against the insurance company. *Id.* Therefore, the Illinois Supreme Court held that the Insurer's duty to defend was triggered because sending its customer's biometric information to a single third party vendor constituted a "publication" of the information; thus, the BIPA class-action alleged a "personal injury" or "advertising injury" under the plain language of the business owner's policy.

The Illinois Supreme Court next found that the violation of statutes exclusion in the policy did not bar coverage. The Insurer argued the exclusion should apply because its express language barred coverage for lawsuits involving violations of a statute that "prohibits or limits . . . communication or distribution of . . . information," and BIPA prohibits distributing individual's personal biometric information. However, the Illinois Supreme Court rejected this argument and found that the first two paragraphs of the violation of statutes exclusion was focused on statutes that regulate communications (*i.e.* the TCPA and the CAN-SPAM Act), whereas BIPA "does not regulate methods of communication but regulates the collection, use, safeguarding, handling, storage, retention, and destruction of biometric identifiers and information." *Id.* at ¶ 55 (citing 740 ILCS 14/5(g)). The Illinois Supreme Court additionally noted that "regulating telephone calls, faxes, and e-mails is fundamentally different from regulating the collection, use, storage, and retention of biometric identifiers and information (fingerprints, retina or iris scans, voiceprints, or scans of hand or face geometry)." *Id.*

Further, the Illinois Supreme Court found that under the doctrine of *ejusdem generis*, because paragraphs 1 and 2 of the violation of statutes exclusion related to statutes regulating communications, the third paragraph's catch-all provision must also relate to other statutes that regulate communications. *Id.* at ¶¶ 55-58. The Illinois Supreme Court then held that "since [BIPA] is not a statute of the same kind as the TCPA and the CAN-SPAM Act and since [BIPA] does not regulate methods of communication, the violation of statutes exclusion does not apply." *Id.* at ¶ 58.

As a result, the Illinois Supreme Court affirmed the trial court and appellate court's rulings that the Insurer owed a duty to defend the Insured under the plain language of the policy.

Takeaway

BIPA class-action lawsuits have the potential to result in substantial losses, as shown by Facebook's historic $650 million settlement, as well the numerous other recent BIPA settlements. Moreover, hundreds of new BIPA class-action lawsuits are filed every year. Therefore, both insurers and insureds need to be aware that the Illinois Supreme Court has established that insurance companies may owe a duty to defend their insureds against BIPA class-action lawsuits pursuant to the language within their general liability insurance policies. Insurance companies in particular should be aware of the Illinois Supreme Court's ruling and analyze the language within their own policies to determine their risks with regard to future defense and indemnity payments that may result from potential BIPA class-action lawsuits against their insureds. ■

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As COVID-19 Conditions Improve, Is It Time for Litigators to Re-Evaluate The Use of Virtual Testimony?

Lillian Grappe Lamphere, Attorney

In many ways, America seems to be turning a real corner in the COVID-19 pandemic, which has significantly altered our lives over the past year. Indeed, with the widespread availability of vaccines, people have begun returning to normal activities such as air travel, in-office working, weddings, and even shaking hands. However, for attorneys in some parts of the country, practice remains anything but "normal."

In-person jury trials in many courts across the country remain canceled or postponed with courts turning to virtual hearings and (in some cases) trials as a substitute.[1] While such accommodations were widely granted over the past year, a debate as to the sufficiency of such remote testimony has arisen.[2] Of course, virtual testimony is not an equivalent substitute for live, in-person testimony.[3] In fact, both the legal and scientific communities recognize the shortcomings of virtual testimony, particularly for direct and cross-examination of witnesses.

While Federal Rule of Civil Procedure 43(a) and similar state court procedural rules allow courts to accept testimony by contemporaneous remote transmission for good cause in compelling circumstances, provided appropriate safeguards are in place, this practice is an exception to the general rule that that "[i]n every trial, the testimony of witnesses shall be taken in open court."[4] In fact, the advisory committee's notes on the 1996 amendments to Federal Rule of Civil Procedure 43 make clear that, "The importance of presenting live testimony in court cannot be forgotten. The very ceremony of trial and the presence of the fact-finder may exert a powerful force for truth telling. The opportunity to judge the demeanor of a witness face-to-face is accorded great value in our tradition."[5]

Powerhouse Points

- In-person proceedings in many courts remain canceled or postponed with courts continuing to rely on virtual proceedings as a substitute.
- Virtual testimony is not an equivalent substitute for live, in-person testimony.
- Procedural rules allow courts to accept testimony by contemporaneous remote transmission for good cause in compelling circumstances, provided appropriate safeguards are in place.
- There have been significant advancements in managing the threat of COVID-19, which may be shifting the "good cause" analysis.
- How should litigators, as client advocates, respond to opponents continued preferences for virtual trial and deposition testimony?

State courts have likewise recognized that "it [is] important for the integrity of the process for the parties to present live, in person testimony."[6]

Moreover, peer-reviewed scientific studies have found that remote testimony can affect the fact finder's witness credibility determination and perceptions.[7] In addition to the

1 *Federal Courts Respond to Covid-19: Live Map*, Bloomberg Law, https://news.bloomberglaw.com/us-law-week/arguments-axed-access-limited-courts-respond-to-covid-19-map (last visited Jun. 14, 2021); Justia, *Court Operations During COVID-19: 50-State Resources*, https://www.justia.com/covid-19/50-state-covid-19-resources/court-operations-during-covid-19-50-state-resources/ (last visited Jun. 14, 2021); Christopher Green and Sara Fish, Law360, *Weighing The Virtual Courtroom Option in Civil Cases* (Aug. 19, 2020, 4:45 PM), https://www.law360.com/articles/1302546/weighing-the-virtual-courtroom-option-in-civil-cases; Meghann Cuniff, *Judges differ on when it's safe to hold in-person jury trials,* ABAJournal (February 1, 2021, 3:35 AM), https://www.abajournal.com/magazine/article/judges-differ-on-when-its-safe-to-hold-in-person-jury-trials ("No national policies exist regarding in-person proceedings, resulting in vastly different approaches to jury trials during the pandemic.").

2 Norma C. Izzo, *How Litigators Are Confronting COVID in the Courtroom* (August 31, 2020), https://www.americanbar.org/groups/litigation/committees/trial-practice/articles/2020/covid-19-video-testimony-courtrooms/.

3 *U.S. v. Lawrence*, 248 F.3d 300, 304 (4th Cir. 2001) ("[V]irtual reality is rarely a substitute for actual presence and that, even in an age of advancing technology, watching an event on the screen remains less than the complete equivalent of actually attending it.").

4 Fed. R. Civ. P. 43(a); see Wis. Stat. § 807.13(2).

5 Fed. R. Civ. P. 43 advisory committee's notes to 1996 amendment; see also Stoner v. Sowders, 997 F.2d 209, 213 (6th Cir. 1993) *("[T]he jury and the judge never actually see the witness. The witness is not confronted in the courtroom situation. The immediacy of a living person is lost. In the most important affairs of life, people approach each other in person, and television is no substitute for direct personal contact.").*

6 *In re Shaianne D.*, 2012 WI App 118, ¶ 18, 344 Wis. 2d 521, 822 N.W.2d 737; see, e.g., *Kelly v. Kelly*, 445 S.W.3d 685, 694 (Tenn. 2014) ("There are important reasons why live, in-person testimony is more desirable than remote testimony" and listing frequently cited reasons).

7 Sara Landström, *Children's truthful and deceptive testimonies: How camera perspective affects adult observers' perception and assessment*, 14 Psych., Crime & Law 5 (2008), https://www.tandfonline.com/doi/abs/10.1080/10683160701580107?src=recsys&journalCode=gpcl20&; Sara Landström, *Witnesses appearing live versus on video: effects on observers' perception, veracity assessments and memory*, 19 Applied Cognitive Psych. 7 (2005), https://onlinelibrary.wiley.com/doi/abs/10.1002/acp.1131; Alicia Bannon and Janna Adelstein, *The Impact of Video Proceedings on Fairness and Access to*

disadvantages remote testimony places on the tribunal, virtual testimony arguably deprives the adverse party of its due process right to confront a witness through cross-examination.[8] Given these inadequacies of virtual testimony, "remote transmission is to be the exception and not the rule[.]"[9] Yet, the opposite has proved true over the last year and a half (and with good reason).

First, it need not be an all or nothing equation. Courtrooms across the country have come up with creative solutions to prevent disease spread such as installation of plexiglass barriers, HEPA filters, limiting public attendance, transparent face shields, juror COVID testing, and social distancing procedures.[10] In fact, with the proper precautions, in-person jury trials have proceeded with success during the pandemic and improved conditions would seem to further encourage their return.[11]

Litigants seeking to hold in-person proceedings could address their opponents' safety concerns with the promise of limited attendance, covering the costs of outfitting the tribunal with safety equipment, and abiding by social distancing and/or testing procedures. Should such overtures prove unfruitful, one alternative recently proposed by counsel in the United States District Court for the Southern District of New York is to require individuals seeking to avoid in-person trial testimony to disclose their vaccination status to the tribunal.[12]

Because vaccinated individuals are at low risk of contracting and transmitting COVID-19 infections, litigants could file motions with the court requesting their opponent demonstrate why they should be denied in-person, socially-distanced testimony. To protect the parties' and attorneys' privacy interests, litigators could offer to submit proof of vaccination status for in camera review to the tribunal.

Given the importance of live testimony, the improving COVID-19 conditions, and opening trends across the country, perhaps it is time for attorneys to re-evaluate whether virtual testimony remains necessary in all circumstances. ■

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Justice in Court, Brennan Center for Justice (Sept. 10, 2020) https://www.brennancenter.org/our-work/research-reports/impact-video-proceedings-fairness-and-access-justice-court (collecting and summarizing existing scholarship on the effects of video technology in court proceedings).

8 *Union Auto. Indem. Ass'n v. Capitol Indem. Ins. Co.,* 310 F.2d 318, 321 (7th Cir. 1962); *In re Shaianne D.,* 2012 WI App 118, ¶ 18 (denying a party's request to permit remote testimony at trial, explaining "[remote testimony] would not ensure that all of the due process rights of all of the litigants are properly observed"); see Greene v. McElroy, 360 U.S. 474, 496 (1959) (noting in-person cross-examination is particularly necessary "where the evidence consists of the testimony of individuals whose memory might be faulty or who, in fact, might be perjurers or persons motivated by malice, vindictiveness, intolerance, prejudice, or jealousy").

9 Fed. R. Civ. P. 43(a); Lopez v. NTI, LLC, 748 F. Supp. 2d 471, 479 (D. Md. 2010) (citing Fed. R. Civ. P. 43(a)).

10 Matt Reynolds, *6 tips from infectious disease experts for in-person court proceedings*, ABAJournal (Feb. 23, 2021, 12:57 PM), https://www.abajournal.com/web/article/six-tips-from-infectious-disease-experts-for-in-person-court-proceedings.

11 Christian Nolan, *The Verdict Is In…What an In-Person Trial Is Like During COVID-19*, New York State Bar Association (November 17, 2020), https://nysba.org/the-verdict-is-inwhat-an-in-person-trial-is-like-during-covid-19/; Meghann Cuniff, *supra* note 1 ("Despite reports from federal courts of in-person jury trials being held safely, many judges across the country are still deliberating whether to hold in-person jury trials at all.").

12 Debra Cassens Weiss, Reluctant trial witnesses should disclose vaccination status to judge, motion says, ABA Journal (Mar. 31, 2021, 12:15 PM), https://www.abajournal.com/news/article/reluctant-trial-witnesses-should-disclose-vaccination-status-to-judge-motion-says.

Cosmetics Containing CBD - How Regulated Should They Be?

Kimberly A. Beis, Partner

Cosmetic products containing CBD are everywhere! Lotions, bath salts, serums, powders, shampoo, makeup. Deciding which ingredients to include in a product, how and where to manufacture, and what marketing claims to make are important and at times difficult decisions for a company to make.

When considering the inclusion of CBD in a cosmetic product, the decisions can become even more complicated due to the lack of guidance from FDA and the differing stances of many states. But given consumer interest in and demand for CBD products, it can also be an attractive option for many companies. While the inclusion of CBD in a product can be complicated from a legal and regulatory standpoint, it is not impossible, and may very well be worth it – when done thoughtfully.

In order to properly label, market and sell a cosmetic product containing CBD, it is essential to get advice in order to limit the risk of legal action for any mistakes or misunderstandings. Even if a product is already on the market, it is never too late to reevaluate your labeling and/or marketing, as well as where and how a product is sold.

The FDA Has Not Banned CBD in Cosmetics - but Has Not Explicitly Approved of it Either

First and foremost, it is important to understand how the FDA defines a "cosmetic." Cosmetics are defined by the FDA as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap." However, if a product is intended to affect the structure or function of the body, or to diagnose, cure, mitigate, treat or prevent disease, it is considered a drug, or possibly both a cosmetic and a drug, even if it affects the appearance. When a product is considered a drug, or both a drug and a cosmetic, a company may get a warning letter from FDA – which is becoming more common in relation to CBD products.

Powerhouse Points

- While the FDA has not explicitly banned CBD in cosmetics, it does maintain enforcement actions against companies that market their products incorrectly. The European Union has recently taken steps towards allowing CBD as an ingredient in cosmetics in its member states.
- Despite this progress, different states have different rules on CBD, and organizations that want to sell cosmetics nation-wide need to take into account these differences.

Thus far, FDA enforcement relating to CBD has focused on prohibiting companies from making any type of health claims about CBD, as such claims cause the FDA to classify that product as a drug.

CBD Warning Letters

In March 2021, the FDA sent warning letters to two companies for their CBD "pain relief" products. Because these products claimed to relieve pain, they were considered to be a misbranded drug. These two enforcement letters are particularly interesting because of the generic nature of the claims relating to "pain." Prior to these warning letters, most CBD product warning letters were issued because of claims to treat or cure diseases, like cancer or COVID-19.

This arguably, makes enforcement of cosmetics containing CBD products the same as enforcement relating to all cosmetics. The FDA is concerned about how the product is marketed; more specifically, that the product is not being marketed as a drug.

Marketing of Cosmetics - FDA's Position

CBD has not been explicitly prohibited in cosmetic products by the FDA, and as noted above, enforcement relating to CBD containing products has been focused on products being misbranded or adulterated due to claims of treating, preventing or curing a disease.

The FDA will deem a cosmetic misbranded if it is labeled in a false or misleading way, does not comply with labeling requirements, or is made or filled in a deceptive manner. This is true for all cosmetics, whether they contain CBD or not.

The FDA has not determined that a cosmetic containing CBD is automatically adulterated or misbranded – but the FDA does appear to be paying close attention to the CBD market. As such, it is increasingly important for companies marketing cosmetic products containing CBD to ensure their marketing claims are appropriate for a cosmetic product.

CBD Added as a Legal Cosmetic Ingredient in the EU CosIng Database

The EU has stated, in its CosIng guidelines, that CBD, "derived from extract or tincture or resin of cannabis", is a legal cosmetic ingredient. Prior to this decision (which took place in February 2021), only synthetic CBD was explicitly allowed as a cosmetic ingredient. This revision allows for plant-derived CBD to be in products to serve the function of anti-sebum, antioxidant, skin conditioner and skin protectant.

This revision does not give carte-blanche to any company wanting to include CBD in its cosmetic products however. The EU CosIng database is a guideline for EU member states, when those states are determining their own regulations concerning cosmetics. Many member states have their own CBD laws and regulations, which do not always follow CosIng or other EU member states. In addition each member state has its own manufacturing, labeling and marketing requirements. The lack of consistency across member states makes it difficult for companies selling cosmetics containing CBD to freely trade those products throughout the EU.

However the Court of Justice of the European Union (CJEU) recently ruled that CBD derived from the hemp plant is not a narcotic, and can therefore be traded between EU member states. As rulings by the CJEU are binding on all EU members states, this decision will likely result in more consistency in rules, regulations, and enforcement relating to CBD cosmetics in EU members states.

California Says "No" to CBD in Cosmetics - Through an FAQ

In January 2021, the California Department of Public Health (CDPH) issued a revision to its FAQs relating to inclusion of CBD in various products. The FAQ explicitly adopts the FDA's position banning CBD as a food additive, dietary supplement, or pet food, and then, surprisingly, expressly states CBD is an adulterant in food AND cosmetics.

California's Sherman Food and Drug Law provides that a food product is adulterated if it has any food additive that is unapproved, and that a cosmetic is adulterated if it has any "poisonous or deleterious substance that may render it injurious to user under the conditions of the use prescribed in the labeling or advertisement of the cosmetic, or under conditions of use as are customary or usual."

Unlike the FDA, the CDPH has explicitly stated CBD (from hemp or any other source) is not allowed in items regulated by the Food and Drug Branch of CDPH – which includes food, drugs and cosmetics. This position is far more restrictive than the FDA regulations, but is quite clear – CBD is not approved for use in cosmetics.

Interestingly, California did not alter its regulations through a rule making process, but merely by issuing an updated FAQ. Many states are working hard to regulate CBD products – and ensure they are safe for the public - and the hope is California and FDA will do the same. Enforcement of cosmetics containing CBD in California will be important to watch, particularly given the number of products already on the market.

As the CBD Industry Continues to Grow, One State is Not Like the Other

Currently, each of the 50 states approaches products containing CBD in their own way, and while there is a great deal of overlap across many states, there is also a great deal of divergence. As noted, California has recently banned CBD from food and cosmetics products. Colorado requires very specific labeling requirements. In Idaho, CBD is entirely illegal.

The CBD market has grown exponentially in the past few years, and while uniform regulation is hoped for (and somewhat expected), as of right now, this growing industry faces some complexities for nation-wide sales. If a company intends to sell a product containing CBD throughout the United States, it is important to conduct the necessary due diligence for each of the 50 states to limit risk and exposure to enforcement actions from regulatory agencies as well as consumer civil lawsuits. ■

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Will TRIPS Waiver of IP Protection for COVID-19 Vaccines Serve Global Need?

Delphine Knight Brown, Partner

Powerhouse Points

- Proposed TRIPS waivers of IP protection for COVID-19 vaccines apply to copyrights, industrial designs, patents and trade secrets.
- Compulsory IP licenses issued in past public health emergencies have not required the disclosure of trade secrets.
- Compulsory IP licenses may raise jurisdictional, constitutional and enforcement issues.
- Even with waiver of IP protections, vaccine production is extremely complex and manufacturers face raw materials and equipment shortages.

In October 2020, as the race for a COVID-19 vaccine forged ahead, and the global pandemic raged across the globe, World Trade Organization (WTO) members India and South Africa proposed that intellectual property protections for COVID-19 vaccines be temporarily waived and IP enforcement suspended.[1] The waiver proposal, which was recently updated on May 25, 2021, would apply to copyrights, industrial designs, patents and trade secrets. The proposal is intended to allow WTO member countries to export vaccines manufactured by generic pharmaceutical without risking challenges under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which requires WTO member countries to recognize protections for IP rights. It is worth noting that, prior to the TRIPS agreement, more than 50 countries did not recognize patent protection for pharmaceutical products.

Last month saw a significant realignment of positions regarding the TRIPS waiver proposal. The United States now supports (having initially opposed) waiving IP protections for COVID-19 vaccines.[2] The TRIPS waiver proposal is still opposed by the European Union, United Kingdom, Switzerland and Japan. Not surprisingly, these countries are home to major pharmaceutical companies. The European Union has offered a counterproposal to waive IP protections by easing export restrictions for vaccines and providing for the issue of compulsory licenses.[3] Earlier this month, WTO members agreed to focus on language in both TRIPS waiver proposals with the lofty goal of reaching consensus in late July.

All 164 WO member countries must agree on the text and any approved waiver.

The TRIPS waiver proposals pit upholding patent protections against COVID-19 public health needs. To date, the G-20 countries have only agreed to voluntary sharing of IP,[4] highlighting one of the main obstacles to achieving more support for the TRIPS waiver proposals: whether pharmaceutical companies can and should be required to disclose trade secrets.

Trade secrets are considered highly confidential proprietary information by pharmaceutical companies and often relate to research and development processes and pipelines, not merely single products. For example, the mRNA vaccines produced by Pfizer and Moderna employed technology that has been previously utilized in biomedical research but the specific manufacturing process likely can't be easily replicated. Therefore, in order for other companies to reproduce the vaccines, pharmaceutical companies might need to disclose know-how, including training, technical assistance, materials and company documents, all of which are typically considered protected trade secrets.

1 Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, TRIPS Communication IP/C/W/669 (October 2, 2020).

2 *See* Statement from Ambassador Katherine Tai on the COVID-19 TRIPS Waiver (May 5, 2021), available at https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver.

3 *See* Bloomberg, EU's Trade Response to Pandemic Stops Short of Vaccine IP Waiver, available at https://www.bloomberg.com/news/articles/2021-06-03/eu-s-trade-response-to-pandemic-stops-short-of-vaccine-ip-waiver.

4 Health Policy Watch, G20 Leaders Promise to Share More Vaccines While EU Digs in Against TRIPS Waiver (May 21, 2021), available at https://healthpolicy-watch.news/g20-leaders-promise-to-share-more-vaccines-while-eu-digs-in-against-trips-waiver.

Experts agree that the sharing of know-how is critical to scaling up COVID-19 vaccine production and developing second generation vaccines to address variants. However, there is no precedent for forcing pharmaceutical companies to involuntarily disclose trade secrets. Compulsory patent licenses were issued in the past for to boost production of AIDS and HIV drugs, but even those licenses did not require disclosure of trade secrets.

Compulsory licensing could result in more litigation than compliance when trade secrets are at issue, especially when such information has application beyond current COVID-19 vaccines. To date, no vaccine company has voluntarily shared its know-how through the World Health Organization's COVID-19 Technology Access Pool (C-TAP).

The May 25 revisions to the initial TRIPS waiver proposal sought to limit its effective time period to "at least three years," but broadened its application from "preventing, treating and containing COVID-19" to "health products and technologies" related to the "prevention, treatment or containment of COVID-19."[5] The revisions seem unlikely to result in additional support for other than the voluntary sharing of IP rights. The U.S. would likely only support a more limited waiver covering vaccine IP rights. The EU has indicated a willingness to negotiate a waiver of limited duration consistent with its counterproposal.

Despite the current U.S. administration's apparent support for waiving IP protection for COVID-19 vaccines, the response in the U.S. to the proposed broader waiver would most certainly involve intense lobbying by pharmaceutical companies to reverse or severely narrow its effect. The U.S. Congress has already introduced legislation to require Congressional approval of any waiver, and prohibit the use of federal funds to support a waiver.[6] If the U.S. government seeks to enforce a TRIPS waiver, the takings clause of the Fifth Amendment to the U.S. Constitution could be used by U.S. companies as a sword to prevent the loss of intellectual property rights without compensation. In addition, compulsory licenses issued by foreign governments to U.S.-based pharmaceutical companies would be the subject of jurisdictional challenges and lack effective enforcement mechanisms.

The TRIPS waiver proposals have been under discussion for over eight months with no end in sight, and will likely fall prey to months, if not years, of legal challenges if approved. Additionally, despite India and China developing mRNA vaccine candidates, when one considers the intellectual property landscape for mRNA vaccines, a handful of pharmaceutical companies still hold half of the patent applications.

Though a TRIPS waiver might free up untapped capacity for increased vaccine production to meet the huge unmet need, it seems that government and private sector partnerships could be forged much more expeditiously and result in the desired rapid ramp up of COVID-19 vaccine production. For example, Moderna and Samsung Biologics recently announced an agreement for fill-and-finish manufacturing of Moderna's COVID-19 vaccine.[7]

When the IP waiver concept was first proposed last October, Moderna agreed not to enforce its COVID-19 related patents during the pandemic. But despite Moderna's voluntary waiver of its IP rights, no other company has stepped up to manufacture the Moderna vaccine. The most significant obstacle to COVID-19 vaccine supply is not just the IP rights that companies have obtained, or are pursuing, but rather the lack of raw materials and manufacturing facilities to produce the vaccines. Currently, there are shortages of raw materials and equipment used to make vaccines and biological products.

Unlike drug manufacturing, vaccine production processes are extremely complex and difficult to develop without support from current manufacturers. Additional manufacturers would need to have or acquire skilled expertise in mRNA technology and create or reconfigure manufacturing sites. Manufacturing vaccines requires additional processing steps and testing to assure quality and consistency. Manufacturing vaccines will also likely use the patented technology of other companies, who have not waived their IP rights. Investment in manufacturing is also an important piece of the solution. Whether existing companies can retool facilities and jump start manufacturing or new facilities need to be created through investment will be outcome determinative.

There is little doubt that the waiver proposals would at the very least up-end the existing incentives, including the prospect of future pharmaceutical innovation and development of products, that resulted in the rapid development and approval of COVID-19 vaccines. Moreover, the TRIPS waiver proposals may not have the desired effect of boosting COVID vaccine production and availability of mRNA vaccines. On the other hand, recent attempts at voluntary licensing and technology transfer agreements related to adenovirus vector technology have resulted in increased vaccine production and availability. A TRIPS waiver may not be as effective for more complex vaccine production.

Scaling up COVID-19 vaccine production is not a one-size-fits-all proposition. Ensuring equitable availability and delivery complicates the matter further.

5 Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, TRIPS Communication IP/C/W/669/Rev. 1 (May 21, 2021).

6 *See*, e.g., H.R. 3236 and 3035, 117th Cong.

7 *See* https://www.prnewswire.com/news-releases/moderna-and-samsung-biologics-announce-agreement-for-fill-finish-manufacturing-of-modernas-covid-19-vaccine-301297280.html.

Coordination and collaboration will be required within a complex network of investing in technology transfer, contracting existing and new manufacturing facilities, sourcing materials, and pooling procurement facilities. The negotiators and drafters of any TRIPS waiver have a difficult task to craft it into the cornerstone of an effective solution to the known problems of unmet need, and supply and availability, while also anticipating issues yet to arise concerning sustainability of supply, intellectual property rights for COVID-19 tests and treatments, and sharing of research. The next several months will determine whether a TRIPS waiver can be successfully negotiated, practically implemented, and make a timely and effective difference in COVID-19 vaccine availability. ■

Delphine Knight Brown is a Partner in the firm's Litigation Practice Group, and Intellectual Property Litigation Group. With over twenty years of trial experience, Delphine's practice focuses on complex intellectual property and technology cases, with extensive experience in the life sciences industry.

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Delphine Knight Brown, New York
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Jacob R. Schuhardt, Chicago
Jake is an Associate in the Litigation Practice Group. Jake has experience conducting research and writing legal memoranda on a variety of issues including SEC disclosure requirements, defamation law, and real estate lease terms.

Katie L. Schwartz, New York
Katie is an Associate in Freeborn's Litigation and Labor and Employment Practice Groups. Katie has commercial and business litigation experience, and has represented clients in state and federal courts.

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Hailey is an Associate and a member of the firm's Litigation and Insurance Practice Groups. She focuses her practice on representing individuals and organizations in insurance defense matters through all phases of both state and federal litigation.

Chambers USA Ranks 5 Freeborn Practice Areas and 11 Firm Attorneys in 2021 Legal Industry Guide

Chambers AND PARTNERS

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- Real Estate

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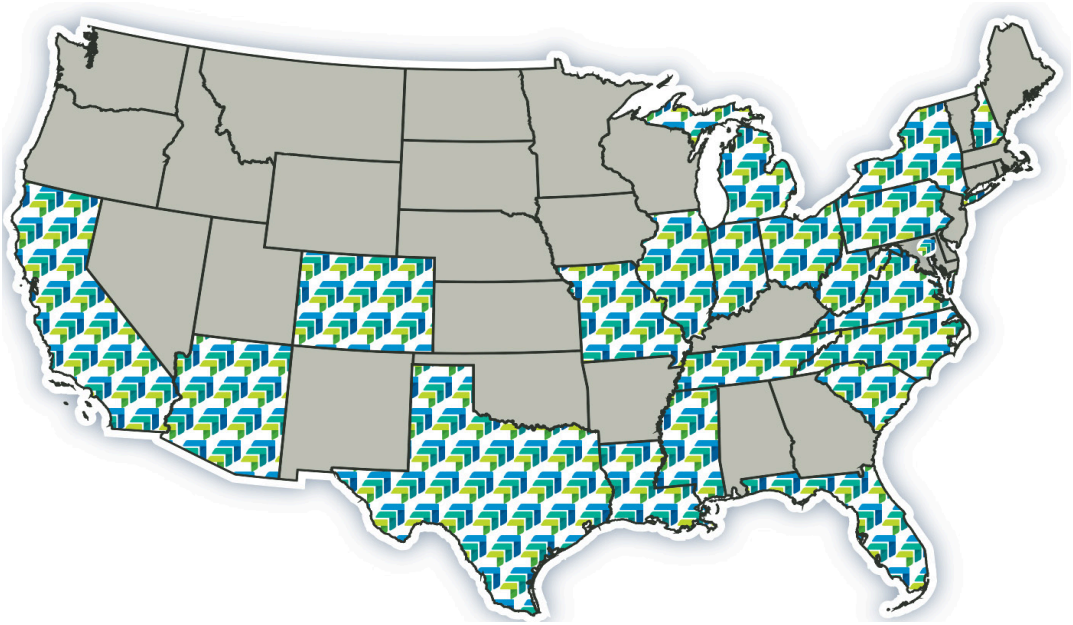

HIGHLIGHTED WINS

- A team of Freeborn attorneys, in partnership with the National Immigrant Justice Center, prevailed on behalf of a pro bono client in an asylum trial against the government's robust efforts to deport our client back to Cameroon. The client fled Cameroon after the military arrested and tortured her because of her political identity, and for participating in a peaceful protest against the marginalization and unjust treatment of Southern Cameroon. Even after she fled, the military continues to search for and threaten her, so she cannot return for fear she will be imprisoned or murdered. The client was recently granted protection in the U.S.

- Secured summary judgment on behalf of closely held corporation in contentious breach of fiduciary duty claim.

- Obtained reversal of an unfavorable decision on appeal, resulting in case going back to trial court for decision on trial regarding avoidance of fraudulent transfers under Pennsylvania state law.

- Successfully prevailed on motion to dismiss a breach of contract claim with prejudice on behalf of client North Carolina company. Plaintiff claimed that under its business brokerage agreement, it was entitled to a commission when defendant client completed an internal company restructuring. The court found that while the transaction at issue may have qualified as a commission triggering transaction, plaintiff's claim was defeated by defendant's evidence and dismissal was warranted with prejudice because plaintiff failed to comply with Supreme Court Rule 191(b). Plaintiff's motion to reconsider was denied. (*Circuit Court of Cook County, Illinois*)

- Successfully dismissed 7-count complaint containing claims of breach of fiduciary duty, conspiracy, and violations of the Illinois Securities law, as well as defeated a motion for reconsideration of the dismissed claims, in a lawsuit involving members of a local start-up company. (*Circuit Court of Cook County*)

- Successfully handled two related legal malpractice cases involving both trustee and receiver issues which were vigorously litigated by plaintiff for almost three years. Plaintiff claimed the amounts in controversy were above seven figures, but on the eve of the first trial, the plaintiffs voluntarily dismissed both cases with prejudice, with our client paying nothing. (*Florida Circuit Court*)

- Obtained emergency preliminary injunction and temporary restraining order on behalf of client, Paragon Insurance Holdings, LLC, enjoining Allied World Insurance Company from its attempt to both terminate a Program Management Agreement with Paragon and take Paragon's protected trade secret client and customer renewal information impacting the insurance placements of over 950 wineries and breweries across the country insured under a nationwide specialty insurance program. *Paragon Insurance Holdings LLC v. Allied World Insurance Company*, No. 19 cv 7238 (S.D.N.Y. 2019).

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