

## IP and FDA Regulation of De Novo Medical Devices

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If recent changes to the US Food & Drug Administration's (FDA's) authority are an indication, the future of medical device regulation could largely be shaped by intellectual property (IP). In an effort to “accelerate innovation of and patient access to novel technologies,”<sup>1</sup> the FDA now has authority to clear medical devices under its “De Novo Pathway,” a shortened path to market for new, innovative devices.<sup>2</sup> This authority also includes the ability for follow-on applicants (referred to as “510(k) applicants” after the pertinent statutory section) to use approved De Novo devices as predicates upon which to base their devices’ safety and efficacy.<sup>3</sup> But the Agency’s guidance in the area – in combination with devices’ increasingly technological sophistication – put De Novo devices’ IP protections at the forefront of the approval process. This raises a host of questions about the intersection of IP and medical devices, including standard essential patents covering medical devices, IP protections for medical device software, and products liability’s relationship with medical device IP.<sup>4</sup>

Section 9.1 of this chapter provides a brief overview of medical device regulation in the United States and, in particular, the De Novo and 510(k) premarketing

<sup>1</sup> Aaron S. Kesselheim & Thomas J. Hwang, Breakthrough Medical Devices and the 21st Century Cures Act, 164 *Annals Internal Med.* 500, 501 (2016).

<sup>2</sup> See US Food & Drug Admin., Acceptance Review for De Novo Classification Requests: Guidance for Industry and Food and Drug Administration Staff [hereinafter “De Novo Acceptance Guidance”] (Sept. 9, 2019), <https://www.fda.gov/media/116945/download> [<https://perma.cc/7YBQ-FWUM>]; US Food & Drug Admin., De Novo Classification Process (Evaluation of Automatic Class III Designation): Guidance for Industry and Food and Drug Administration Staff [hereinafter “De Novo Classification Guidance”] (Oct. 30, 2017), <https://www.fda.gov/media/72674/download> [<https://perma.cc/8US4-QEG7>].

By convention, FDA capitalizes “De Novo” in its guidance documents, a convention we follow here.

<sup>3</sup> See 21st Century Cures Act, Pub. L. No. 114–255, 130 Stat. 1033 (2016); De Novo Classification Guidance, *supra* note 2, at 5 (“The granting of the De Novo request allows the device to be marketed immediately, creates a classification regulation for devices of this type, and permits the device to serve as a predicate device.”); US Food & Drug Admin., Premarket Notification 510(k) (Sept. 27, 2018), <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k> [<https://perma.cc/EDK4-SB9N>] (“A legally marketed [predicate] device is a device . . . that was granted marketing authorization via the De Novo classification process”).

<sup>4</sup> JS Sherkow, M Aboy, “The FDA De Novo medical device pathway, patents and anticompetition” *Nature Biotechnology* 38 (9), 1028–1029.

pathways. It includes a discussion of recent FDA guidance in the area that lend themselves to a variety of intellectual property strategies to potentially hinder follow-on 510(k) applications, as discussed in [Section 9.2](#). [Section 9.3](#) examines the implications for such strategies and explores three areas for future attention: standards essential patents covering core technological features of De Novo devices; intellectual property protection for software critical for medical devices; and products liability regimes that incorporate this approval–infringement gambit.

### 9.1 MEDICAL DEVICE PREMARKETING PATHWAYS

Recent attempts to modernize and speed up the FDA’s premarketing clearance and classification process for medical devices have included both new device classifications and new ways of filing abbreviated applications. The FDA’s “De Novo” classification and “Breakthrough Devices” programs, in particular, allow applicants to create entirely new medical device “types,” complete with their own fleet of standardized safety and effectiveness checklists, including sets of specifications on software, hardware, and energy sources.<sup>5</sup> These safety and effectiveness checklists are enumerated for each device type in the FDA’s rolls under “general” or “special controls.” General controls are a list of safety checks required of all medical devices – proper labeling, for example.<sup>6</sup> Special controls, by contrast, are safety and effectiveness checks specific to a device type, e.g., a requirement that external cardiac pacemakers deliver a current at a pulse amplitude no greater than 200 mA.<sup>7</sup> The De Novo pathway, in particular, allows the clearance of devices that can demonstrate a “reasonable assurance” of fidelity to its device type’s general and special controls.<sup>8</sup>

The De Novo and Breakthrough pathways are still a novelty, however, and the vast majority of medical devices – over 85 percent by some metrics – are cleared through what is known as the “510(k) pathway,” named so after the pertinent section in the Food, Drug & Cosmetics Act (FDCA).<sup>9</sup> Up to now, the 510(k) pathway has been the most widely employed medical device premarket submission program since the enactment of the Medical Device Amendments of 1976 to the FDCA.<sup>10</sup> Significant for

<sup>5</sup> De Novo Classification Guidance, *supra* [note 2](#); 21st Century Cures Act, *supra* [note 3](#) (codifying breakthrough device review); US Food & Drug Admin., Breakthrough Devices Program: Guidance for Industry and Food and Drug Administration Staff [hereinafter “Breakthrough Device Guidance”] (Dec. 18, 2018), <https://www.fda.gov/media/108135/download> [<https://perma.cc/P24U-HHHU>].

<sup>6</sup> 21 C.F.R. § 860.3(c)(1) (West 2020).

<sup>7</sup> *Id.* § 860.3(c)(2) (West 2020) (special controls, generally); *id.* § 870.5550(b)(2) (external cardiac pacemakers).

<sup>8</sup> 21 U.S.C.A. § 360c(f)(2)(A)(v) (West 2020).

<sup>9</sup> See US Food & Drug Admin., FY 2018: Performance Report to Congress for the Medical Device User Fee Amendments at 18 <https://www.fda.gov/media/130598/download> [<https://perma.cc/MWU2-JPUT>] (noting that the Agency received 3,591 510(k) notifications during the 2018 fiscal year, compared to 619 applications for other approvals – 85 percent of the total).

<sup>10</sup> See Vinay K. Rathii & Joseph S. Ross, Modernizing the FDA’s 510(k) Pathway, 381 *N. Engl. J. Med.* 1891 (2019); see also Medical Device Amendments of 1976, Pub. L. 94–295, 90 Stat. 539 (1976).

the 510(k) pathway is the process by which a new device is categorized into one of three classes based on its risk: Class I, the least risky devices; Class II; or Class III, the most risky devices.<sup>11</sup> This initial classification determines the requirements a device must meet prior to market introduction. In particular, non-exempt Class I and Class II devices for which a “predicate” device exists can rely on the 510(k) pathway toward clearance if the new device can show it is “substantially equivalent” to the predicate device.<sup>12</sup> By contrast, Class III devices, for the most part, must instead use the significantly more onerous Premarket Approval (“PMA”) pathway, which may require costly clinical tests.<sup>13</sup> Accordingly, over the last forty years, the 510(k) program became the preferred and dominant premarketing pathway for medical device manufacturers, and especially those concerning Class II devices.<sup>14</sup>

In an effort to encourage innovation and competition, the 21st Century Cures Act allows De Novo devices to serve as “predicates” for subsequent 510(k) submissions, so long as such devices use the same general and special controls as their De Novo predicates, and possess, in most cases, “the same” technological characteristics as the predicate De Novo device.<sup>15</sup> This allows the 510(k) applicant to demonstrate “substantial equivalence” between it and the De Novo device.<sup>16</sup> The substance of the substantial equivalence determination is based primarily on satisfying two inquiries: first, “Do the devices have the same intended use?”; and second, “Do the devices have the same technological characteristics?”<sup>17</sup> The result of failing to satisfy both of these inquiries is a “not substantially equivalent” determination, which traditionally automatically classified the new device as a Class III, that is, high-risk, device, depriving the applicant of the convenience, cost, and speed of the 510(k) pathway.<sup>18</sup>

Until recently, this approval structure encouraged applicants to characterize their new medical devices as having the “same intended use” and “same technological characteristics” as a predicate device, independently of their devices’ degree of novelty.<sup>19</sup> Applicants of low- and moderate-risk devices needed to be cautious of introducing significant innovations, however, as these could result in an NSE

<sup>11</sup> 21 U.S.C.A. § 360c(a)(1) (West 2020).

<sup>12</sup> *Id.* § 360c(i).

<sup>13</sup> *Id.* § 360e(b)(1).

<sup>14</sup> Rathi & Ross, *supra* note 11.

<sup>15</sup> See 21 U.S.C.A. § 360c(i) (West 2020) (mandating these requirements for all 510(k) applications).

<sup>16</sup> *Id.* § 360c(f)(2)(B)(i) (West 2020) (authorizing “any device classified under [the De Novo pathway] shall be a predicate device for determining substantial equivalence under paragraph (1)”; De Novo Classification Guidance, *supra* note 2, at 12 (“Once a De Novo request is granted, then the subject device may be used as a predicate for any future 510(k) submissions.”)).

<sup>17</sup> US Food & Drug Admin., The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff Document, at 27 [hereinafter “510(k) Flowchart”] [www.fda.gov/media/82395/download](http://www.fda.gov/media/82395/download) [<https://perma.cc/3DF6-FN29>].

<sup>18</sup> See *id.* at 3 (“A determination that a new device is not substantially equivalent (NSE) to a predicate device results in the new device being classified into Class III.”).

<sup>19</sup> Inst. of Med. of the Nat’l Academies, Medical Devices and the Public’s Health: The FDA 510(k) Clearance Process at 35 Years, [hereinafter IOM 510(k) report] 193–4 (2011) (“The committee found

determination and shunting to the PMA route of approval.<sup>19</sup> Some have argued that – at least for some devices – this encouraged slow and incremental changes to preexisting devices at the expense of radical innovation.<sup>21</sup>

On December 7, 2018, however, the FDA published new draft guidance for the De Novo classification process under the 21st Century Cures Act.<sup>22</sup> The agency followed the guidance with a September 9, 2019 “Acceptance Guidance” to further support the De Novo process as a pathway to classify novel medical devices for which there is no legal marketed predicate device.<sup>23</sup> This alternative pathway for low- and moderate-risk devices (i.e., Class I and Class II devices) is now available for either applicants who received an NSE determination in a prior 510(k) application; or applicants claiming that there is no legally marketed predicate device upon which to base a 510(k) application.<sup>24</sup> This second option, in effect, creates a new regulatory pathway for approval of novel medical devices: the direct submission of a device under a De Novo classification request.<sup>25</sup> 510(k) applicants, in turn, may use these “direct” De Novo devices as predicates for their applications.<sup>26</sup>

At best, this procedure is hoped to accelerate the development of truly novel medical devices. Criticism of the prior regime centered on a flight not to innovation but to mimicry – the fear of innovating too much at the risk of an NSE determination.<sup>27</sup> Allowing the rapid entry of truly novel devices through the De Novo and Breakthrough programs, followed by slight variation and market competition through the 510(k) pathway seeks to encourage both innovation and competition.<sup>28</sup> Whether this will meet its mark remains to be seen. A 2011 Institute of Medicine report raised hopes that the De Novo pathway “offers a potential basis of a better regulatory model for premarket review of Class II devices.”<sup>29</sup> But as of this writing there were fewer than 300 marketed De Novo devices in the United States.<sup>30</sup>

that the 510(k) clearance process was not designed to reward, recognize, or encourage innovation. At most, promotion of innovation was a byproduct of a process that, by minimizing unnecessary regulatory burdens, facilitated the entry into the market of new devices that do not raise novel questions of safety or effectiveness.”)

<sup>20</sup> *Id.*

<sup>21</sup> See Christopher Buccafusco, *Disability and Design*, 95 *NYU L. Rev.* 952, 974–6 (2020) (recounting this with respect to wheelchairs).

<sup>22</sup> De Novo Classification Guidance, *supra* note 2.

<sup>23</sup> De Novo Acceptance Guidance, *supra* note 2.

<sup>24</sup> De Novo Classification Guidance, *supra* note 2, at 4.

<sup>25</sup> *Id.*

<sup>26</sup> *Id.* at 12; see also 21 U.S.C. § 360c(f)(2)(B)(i) (West 2020).

<sup>27</sup> IOM 510(k) Report, *supra* note 20, at 193–4.

<sup>28</sup> *Id.* at 195–6.

<sup>29</sup> *Id.* at 11.

<sup>30</sup> US Food & Drug Admin., *Device Classification under Section 513(f)(2)(de novo)*, [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?start\\_search=1&Center=&](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?start_search=1&Center=&)

## 9.2 INTELLECTUAL PROPERTY CONSIDERATIONS

## 9.2.1 IP and Competition

These premarketing pathways, while rooted in classic considerations of safety and effectiveness, lend themselves to a potential intellectual property strategy with the effect of – or designed for – preventing 510(k) applicants from using De Novo devices as predicates. The strategy begins with the general and special controls certification required for the submission of a De Novo application. The application must include “a description of why . . . general and special controls provide reasonable assurance of safety and effectiveness.”<sup>31</sup> This certification of “reasonable assurance” based on these controls is, of course, the impetus behind the De Novo pathway: if general and special controls really can ensure a device’s safety and effectiveness, then requiring an applicant to demonstrate safety and effectiveness through robust clinical trials even though there is no appropriate predicate is wasteful.<sup>32</sup> Additionally, this certification requirement raises an epistemic problem: how can one be reasonably assured that a device’s special controls will make it safe and effective if there are no other device types like it? To use a new type of pacemaker, for example, how can one know, without robust testing, whether a 200-mA limit, or 250 mA, or 350 mA, provides “reasonable assurance” that the new type of pacemaker is both safe and effective? In an attempt to resolve this question, the FDA, in 2017, began to ask De Novo applicants to propose their own special controls for their own devices.<sup>33</sup> Some of these controls, according to the Agency’s De Novo Acceptance Guidance, can be quite specific and technologically oriented, such as the device’s performance standards, materials used to ensure biocompatibility, its design to ensure safe use, the energy source of the device, data requirements (clinical studies), or its use of software.<sup>34</sup> If these controls are accepted by the FDA, and if the device is approved, as noted above, this establishes a new device type, for which any follow-on applications must either use the same controls or otherwise demonstrate substantial equivalency.<sup>35</sup>

These same technological features, that is, key technological characteristics and the special controls necessarily tied to these technological characteristics through performance standards, can be patented by the De Novo applicant. This establishes an IP barrier of entry for 510(k) applicants wishing to use De Novo devices as predicates for

Panel=&ProductCode=&KNumber=&DenKNumber=&Applicant=&DeviceName=&Type=&ThirdPartyReviewed=&ClinicalTrials=&ExpeditedReview=&Decision=&DecisionDateFrom=&DecisionDateTo=04%2F21%2F2020&DeNovo=on&IVDProducts=&CombinationProducts=&ZNumber=&PAGENUM=500, [<https://perma.cc/HH5A-J59A>].

<sup>31</sup> De Novo Acceptance Guidance, *supra* note 2, at 18.

<sup>32</sup> IOM 510(k) Report, *supra* note 20, at 17–18.

<sup>33</sup> De Novo Classification Guidance, *supra* note 2, at 16 (“For class II devices, provide proposed special controls along with cross-references to other information within the request demonstrating that the device meets these special controls.”).

<sup>34</sup> *Id.* at 18.

<sup>35</sup> *Id.* at 5–6.

their applications: in determining whether a 510(k) application is “substantially equivalent” to its predicate device, the FDA assesses whether the 510(k) device uses the “same technological characteristics” as the predicate, that is, the same “materials, design, [and] energy source, and other device features” of the predicate device.<sup>36</sup> This requires most 510(k) applications to provide “engineering drawings or other figures,” “a complete identification of the detailed chemical formulation used in the materials of construction,” an identification of “energy delivery that is part of the functional aspect of the device,” and a recitation of the device’s “software/hardware features . . . as appropriate for the specific device technology.”<sup>37</sup> To the degree these aspects of the predicate device are patented, this is not just a potential admission of patent infringement but possibly a detailed roadmap of how the De Novo applicant can prove its infringement case.<sup>38</sup>

All is not lost for proposed 510(k) devices that do not use the same technological characteristics as their De Novo predicates; their applicants can still demonstrate substantial equivalency if their devices’ technological characteristics use the same “performance characteristics” and do not “raise different questions of safety and effectiveness.”<sup>39</sup> But these performance characteristics – the De Novo predicates’ “device design, material[s] used, and physical properties” – can substantially overlap with predicates’ special controls, which, if patented, puts 510(k) applicants back in the same trap as before: in order to demonstrate substantial equivalency to the FDA, 510(k) applicants must either admit to patent infringement or confess to the FDA that their proposed devices are not substantially equivalent to their predicates.

In summary, marketers of De Novo devices can tell the FDA which special controls to use to assess their devices, controls that De Novo applicants can then also patent.<sup>40</sup> If these special controls overlap with a De Novo device’s performance characteristics, this makes filing a 510(k) application on the entire De Novo device type impossibly unattractive; the 510(k) applicant must either essentially admit to infringing the De Novo device predicate’s special controls or choose to acknowledge its device is not substantially equivalent, thus sinking their 510(k) application.

### 9.2.2 *An Example: Alternate Controller Insulin Pumps*

Admittedly, this seems like a rather tortuous pathway to quelling competition. But a real-life example proves how easy – and powerful – the strategy can be. As of this

<sup>36</sup> *Id.* at 18–19.

<sup>37</sup> *Id.* at 19–20.

<sup>38</sup> Cf. Shashank Upadhye, *Understanding Patent Infringement Under 35 U.S.C. § 271(e): The Collisions Between Patent, Medical Device, and Drug Laws*, 17 *Santa Clara Computer & High Tech. L. J.* 1, 28 (2000) (“[S]ince the 510(k) process requires a comparison of the products, then perhaps this is also an admission of at least equivalency infringement.”).

<sup>39</sup> 510(k) Flowchart, *supra* note 18.

<sup>40</sup> See *De Novo Classification Guidance*, *supra* note 2, at 16 (“For class II devices, provide proposed special controls along with cross-references to other information within the request demonstrating that the device meets these special controls.”).

writing, Tandem Diabetes Care, Inc. markets, as a De Novo device, the t:slim X2 Insulin Pump, an automatic pediatric insulin pump given the generic device type of “alternate controller enabled infusion pump.”<sup>41</sup> To allow patients control over when they receive insulin, the pump can be operated by a connected smartphone – the “alternate controller” – that raises several concerns over safety and effectiveness for which Tandem identified several special controls.<sup>42</sup> Those controls include, among other things, the “[s]haring of necessary state information between the pump and any digitally connected alternate controllers” and “[a] detailed process and procedure for sharing the pump interface specification with digitally connected devices.”<sup>43</sup> These special controls overlap with the device’s performance controls, which include “validated software protocols intended to ensure secure, accurate, and reliable communication with digital interfacing devices.”<sup>44</sup> As an illustrative example, these aspects of the device’s communication protocols that have been patented by Tandem, which owns over fifty patents covering various aspects of its insulin pump technology.<sup>45</sup> Take, for example, US Patent No. 10,478,551, which claims a broad method “of delivering a medicament bolus with a medical infusion pump” via “a remote consumer electronic device.”<sup>46</sup> Presumably, almost any overlap between the “remote consumer electronic device” enumerated in the claims and a “digitally connected device” that uses a “validated software protocol” to connect to the pump, would at least colorably infringe. US Patent No. 9,833,177, also owned by Tandem, similarly claims a detailed system that includes a “controller communicatively coupled to the pump.”<sup>47</sup> Again, there is likely little daylight between the “secure, accurate, and reliable communication” protocol identified in the device’s performance characteristics and the detailed system for controller communications in the patent. And US Patent No. 9,492,608 claims a variety of methods of “infusing insulin” using a programmed controller, making design-arounds for follow-on applicants difficult.<sup>48</sup>

<sup>41</sup> Letter from Kellie B. Kelm, Acting Director, Division of Chemistry and Toxicology Devices, FDA, to Michael Sarrasin, Senior Director of Regulatory and Clinical Affairs, Tandem Diabetes Care, Inc. (Dec. 3, 2019) [hereinafter “t:slim X2 De Novo Order”] at 1, [www.accessdata.fda.gov/cdrh\\_docs/pdf/18/DEN180058.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/18/DEN180058.pdf) [<https://perma.cc/AD2F-8LS6>].

<sup>42</sup> *Id.* at 3–6.

<sup>43</sup> *Id.* at 4.

<sup>44</sup> US Food & Drug Admin., Evaluation of Automatic Class III Designation For t:slim X2 Insulin Pump with Interoperable Technology – Decision Summary [hereinafter “t:slim X2 Decision Summary”], at 13, [www.accessdata.fda.gov/cdrh\\_docs/reviews/DEN180058.pdf](http://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180058.pdf) [<https://perma.cc/S4G4-HXFJ>].

<sup>45</sup> Conducted doing a search, using the U.S.P.T.O.’s Public PAFT database, on all patents originally assigned to Tandem Diabetes. <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnetahtml%2FFPTO%2Fsearch-adv.htm&r=0&p=1&f=S&l=50&Query=an%2F%22tandem+diabetes%22&d=PTXT> [<https://perma.cc/9DDY-E6HW>].

<sup>46</sup> US Patent No. 10,478,551, at col. 14, ll. 10–11.

<sup>47</sup> US Patent No. 9,833,177, at col. 14, l. 53.

<sup>48</sup> US Patent No. 9,492,608, at col. 14, l. 44.

Ultimately, any 510(k) applicant seeking to market a follow-on alternate controller enabled infusion pump would need either to admit it uses the same “process and procedure for sharing the pump interface specification” with the controller – a likely admission of infringement of Tandem Diabetes’ patents – or that it uses different special controls but nonetheless hews to the device’s performance characteristics – which are also patented. Denial on both counts, under the FDA’s own guidelines, means the two devices are not substantially equivalent. To be clear, there is currently one approved 510(k) application for an “alternate controller enabled infusion pump” – currently marketed by Insulet Corporation, the Omnipod DASH<sup>49</sup> – but it seems clear that Tandem Diabetes considers Insulet to be a direct competitor.<sup>50</sup> Insulet’s 510(k) application, meanwhile, states that while it has different technological characteristics from Tandem’s device, it nonetheless meets the predicate’s performance controls.<sup>51</sup> Whether this will result in a patent infringement suit, or not, remains to be seen, but for now, the pathway presented for any follow-on developer, as with Insulet, seems fraught.

### 9.3 MORE COMPLEX STRATEGIES

In some sense, the anticompetitive trap described above is simple: device manufacturers use patents to protect the very controls required for regulatory approval. But several areas of intellectual property practice intersect with this strategy in complex ways. Standard essential patents trouble the relationship between IP and device requirements. IP protection covering medical device software may be both better and worse for follow-on applicants. And patents may exacerbate the role that products liability plays in designing follow-on devices. These more complex forms of protection further demonstrate the thick ties between IP and medical device approval.

#### 9.3.1 *Standards Essential Patents*

Where patents cover a De Novo device’s special controls or performance characteristics, the patents may be narrow enough to allow 510(k) applicants to design around them. But this becomes greatly complicated – if not downright impossible – where the patents are standards essential patents (“SEPs”) for standards explicitly required to meet safety and efficacy standards.<sup>52</sup> Certifying

<sup>49</sup> Letter from Kellie B. Kelm, Acting Director, Division of Chemistry and Toxicology Devices, FDA, to Julie Perkins, Senior Director, Quality Assurance and Regulatory Affairs, Insulet Corp. (Sept. 20, 2019) [hereinafter “Insulet 510(k)”], available at [www.accessdata.fda.gov/cdrh\\_docs/pdf19/K191679.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf19/K191679.pdf) [<https://perma.cc/68Z2-YY4L>].

<sup>50</sup> Tandem Diabetes Care, Inc., 2019 Annual Report (Form 10-K) (Feb. 24, 2020), at 11, <http://investor.tandemdiabetes.com/static-files/ca84169a-f9d8-4cdd-a759-373252385ea9> [<https://perma.cc/CKU9-3S3G>] (listing “Insulet Corporation” as “Competition”).

<sup>51</sup> Insulet 510(k), supra note 50 at \*6–\*11.

<sup>52</sup> See generally Jorge L. Contreras, *Essentiality and Standards-Essential Patents*, in *The Cambridge Handbook of Technical Standardization Law: Competition, Antitrust, and Patents 2009–30* (Jorge L. Contreras ed., 2017) (reviewing the “essentiality” of patents covering certain standards).



that a 510(k) device meets such a standard is, in essence, a certification of infringement of the SEPs.<sup>53</sup> Here is an example: the FDA's evaluation for alternate controller enabled infusion pumps specifically references the use of a Bluetooth Low Energy radio as the means for reliably and securely connecting the controller to the pump.<sup>54</sup> But the Bluetooth Low Energy technology is, itself, a standard established by the Bluetooth Special Interest Group ("BSIG"), and covered by specific SEPs.<sup>55</sup> As with the patent strategy describe, above, a 510(k) applicant would need to use the same technology and, therefore, obtain a patent license from BSIG. Where the De Novo marketer has participated in developing the standard or contributing its patents to the SEPs, this makes noninfringing 510(k) applications all but a dream.

At the same time, SEPs may present less of a concern than non-SEP patents held by the De Novo device marketer because SEPs are typically licensed on fair, reasonable, and non-discriminatory terms to all comers; injunctions are rare.<sup>56</sup> But a recent policy statement from a variety of government agencies recently questioned the wisdom of dispensing with injunctions for SEPs.<sup>57</sup> If injunctions do begin to become commonplace for SEPs, and if De Novo device marketers robustly participate in setting device standards, 510(k) applicants may find it all but impossible to demonstrate substantial equivalency without facing the threat of an injunction from standards organizations. The future of this area will turn on the effect of this injunction policy and device marketers' participation in standards setting.

### 9.3.2 Software IP

A substantial proportion of the De Novo applications are for SaMDs ("Software as Medical Devices"),<sup>58</sup> "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device" (e.g., a medical device software application that runs on a consumer grade

<sup>53</sup> See Jorge L. Contreras, *Much Ado About Hold-Up*, U. Ill. L. Rev. 875, 881–2 (2019) ("With standards-compliant products, however, the manufacturer's options are more limited; designing around the patent may prevent the product from complying with the standard, thus reducing its functionality or making it unmarketable . . . Thus, in order to sell a standards-compliant product, the prudent manufacturer must obtain permission from the patent holder (known as a license).").

<sup>54</sup> *tslim X2 Decision Summary*, supra note 45, at \*1.

<sup>55</sup> Bluetooth, *Learn About Bluetooth – Radio Versions*, [www.bluetooth.com/learn-about-bluetooth/bluetooth-technology/radio-versions/](http://www.bluetooth.com/learn-about-bluetooth/bluetooth-technology/radio-versions/) [<https://perma.cc/9L44-YQHR>].

<sup>56</sup> Jorge L. Contreras, *Global Rate Setting: A Solution for Standards-Essential Patents*, 94 Wash. L. Rev. 701, 747–8 (2019).

<sup>57</sup> USPTO, DOJ & NIST, *Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments* (Dec. 19, 2019), [www.justice.gov/atr/page/file/1228016/download](http://www.justice.gov/atr/page/file/1228016/download) [<https://perma.cc/VT68-QPXB>].

<sup>58</sup> US Food & Drug Admin., *Device Classification under Section 513(f)(2)(de novo)*, supra note 31; see also Timo Minssen et al., *Regulatory Responses to Medical Machine Learning*, J.L. Biosci., <https://academic.oup.com/jlb/advance-article/doi/10.1093/jlb/lsa002/5817484>.

hardware such as a smartphone).<sup>59</sup> Such De Novo SaMDs raise important questions at the intersection of IP and the medical device premarket pathways in situations where the key computer-implemented inventions are patented and become the key technological characteristics (i.e., the SaMD itself). Even in the cases of “Software *in* a Medical Device” (i.e., software that drives or is required by a hardware medical device to achieve its intended function), the interactions between IP, De Novo, and 501(k) can be problematic. De Novo medical devices typically include software, some of which constitute devices’ core technological characteristics or special controls tight to key performance characteristics. Using the t:slim X2, again, as an example, the insulin pump uses a suite of software to ensure that the device’s various functions – basal delivery, bolus delivery, and occlusion detection, for example – functioned properly.<sup>60</sup> These software controls are, indeed, performance characteristics of the device, follow-on applications of which would need to replicate.<sup>61</sup>

Using IP to protect De Novo devices’ controls and performance characteristics adds nuance to how effectively it could potentially hinder 510(k) applications. With respect to patents, many “software” patents – admittedly, a nettlesome term without clear definition – have been rendered invalid after the Supreme Court of the U.S.’ opinion in *Alice Corp. v. CLS Bank International*.<sup>62</sup> This is true in both post-issuance proceedings at the US Patent and Trademark Office and in litigation in federal court.<sup>63</sup> 510(k) applicants may, therefore, give less credence to software patents covering De Novo devices’ special controls or performance characteristics.<sup>64</sup> In other instances, due to peripheral claiming practice and software patents’ often overly general claim elements, 510(k) may be able to easily design software patents protecting the features of their predicate devices.<sup>65</sup>

But certain forms of software can be copyrighted as well, a substantially more difficult problem for 510(k) applicants.<sup>66</sup> Unlike patents, copyrights’ infringement ambit is central rather than peripheral, rooting itself in whether the accused software

<sup>59</sup> US Food & Drug Admin., Software as a Medical Device, <https://www.fda.gov/medical-devices/digital-health/software-medical-device-samd> [<https://perma.cc/4L2Y-SNJ8>].

<sup>60</sup> t:slim X2 Decision Summary, supra note 45, at 5.

<sup>61</sup> *Id.*

<sup>62</sup> 134 S. Ct. 2347 (2014); see also Ryan T. Holte, The Trespass Fallacy in the “Software Patent” Debate, 65 Fla. L. Rev. F. 46, 49 (2014) (“[T]he debate about ‘software patents’ lacks any clear standard perhaps because the term ‘software patent’ itself lacks any settled definition. Indeed, there is no legal definition for the term ‘software patent’ used by courts and scholars.”).

<sup>63</sup> Stuart Graham & Saurabh Vishnubhakat, Of Smart Phone Wars and Software Patents, 27 J. Econ. Perspectives 67, 70–3 (2013).

<sup>64</sup> Cf. Colleen V. Chien, Holding Up and Holding Out, 21 Mich. Telecomm. & Tech. L. Rev. 1 (2014) (defining “hold out” as the practice of ignoring patent assertion demands because the risk of liability is small).

<sup>65</sup> See Mark A. Lemley, Software Patents and the Return of Functional Claiming, Wis. L. Rev. 905, 947 (2013) (requiring the disclosure of specific algorithms in software patents “will leave room for later entrants to design around the patent and develop different algorithms to achieve the same result”).

<sup>66</sup> See, e.g., Oracle Am., Inc. v. Google Inc., 750 F.3d 1339, 1363–8 (2014) (allowing copyright protection to Oracle’s Java API packages).

possesses “substantial similarity” to the copyrighted one.<sup>67</sup> This also means that “designing around” software copyright is much more difficult.<sup>68</sup> Assuming that software copyrights cover a De Novo device’s special controls or performance characteristic, it would be extremely difficult for a 510(k) applicant to argue that its device is “substantially equivalent” to the De Novo predicate but does not possess “substantial similarity” to its special controls.

With this said, the vitality of copyright covering software – specifically, application program interfaces (“APIs”) – is in dispute. The Supreme Court of the US is, as of this writing, slated to decide the issue in an upcoming case, *Google LLC v. Oracle America, Inc.*, concerning software covering Java APIs.<sup>69</sup> Given APIs’ functional nature, many commentators think the Court will ultimately do away with such protections.<sup>70</sup> Regardless, the case will be important for De Novo and 510(k) applicants alike. Perhaps it is strange to think that the future of medical device competition may substantially turn on the copyrightability of Java APIs, but that may best encapsulate the issues confronting medical device regulation for the twenty-first century.

### 9.3.3 Patents and Products Liability

Even assuming that 510(k) applicants could design around De Novo predicates’ protected controls and performance characteristics, it is not clear how far they would go. Marketers of 510(k) devices, just like marketers for their predicate devices, are liable for design defects in their devices.<sup>71</sup> This is more than a mere worry – medical device products liability cases are some of the most damage-heavy in the American legal system.<sup>72</sup>

Fear of products liability suits has dispirited the adventurousness of many follow-on device manufacturers.<sup>73</sup> Christopher Buccafusco has recently recounted the ploddingly slow incremental improvements behind wheelchairs, even long after their principal patents had expired.<sup>74</sup> Wheelchair manufacturers “continued to make wheelchairs following [the patented] established design . . . [ensuring users]

<sup>67</sup> *Amini Innovation Corp. v. Anthony California, Inc.*, 439 F.3d 1365, 1368 (Fed. Cir. 2006).

<sup>68</sup> See Joseph P. Fishman, *Creating Around Copyright*, 128 *Harv. L. Rev.* 1333, 1386–7 (2015) (noting this problem with copyright’s peripheral claiming structure).

<sup>69</sup> Certiorari Order, *Google LLC v. Oracle Am., Inc.*, No. 18–956 (Nov. 15, 2019), available at [www.supremecourt.gov/orders/courtorders/11519zr\\_8n59.pdf](http://www.supremecourt.gov/orders/courtorders/11519zr_8n59.pdf) [<https://perma.cc/5Q2Q-MQRE>].

<sup>70</sup> E.g., Pamela Samuelson & Clark D. Asay, *Saving Software’s Fair Use Future*, 31 *Harv. J.L. & Tech.* 535 (2018).

<sup>71</sup> Restatement (Third) of Torts: Prod. Liab. § 6(c) (1998).

<sup>72</sup> See, e.g., Tina Bellon, *Johnson & Johnson Hit with \$247 Million Verdict in Hip Implant Trial*, *Reuters* (Nov. 16, 2017), [www.reuters.com/article/us-johnson-johnson-verdict/johnson-johnson-hit-with-247-million-verdict-in-hip-implant-trial-idUSKBN1DG2MB](http://www.reuters.com/article/us-johnson-johnson-verdict/johnson-johnson-hit-with-247-million-verdict-in-hip-implant-trial-idUSKBN1DG2MB) [<https://perma.cc/L7VP-D8HH>].

<sup>73</sup> Buccafusco, *supra* note 22, at 981–2.

<sup>74</sup> *Id.*

would have a difficult time arguing that the product was fundamentally unsafe.”<sup>75</sup> By contrast, follow-on manufacturers expressed the belief that “introducing new products, without established safety records, could subject them to massive liability should people get hurt.”<sup>76</sup> Even with the absence of patent protection and fifty years’ worth of real-world safety data, Buccafusco’s lesson from the wheelchair case is that follow-on manufacturers may not use all of the runway IP otherwise affords them. As applied to De Novo devices, this instruction is likely to have even more force. De Novo devices are, by definition, those without a predicate, devices that are likely to be more novel and potentially more dangerous than wheelchairs. Orthopedic injuries from wheelchair misuse should not be discounted. But faulty insulin pumps are likely to be fatal.

Patents are likely to exacerbate this in the context of 510(k) applications to De Novo devices. If the only path toward noninfringing approval is a radical transition to the predicate device’s design, 510(k) applicants may forgo the opportunity altogether for fear of liability. At the same time, incremental innovation – like that historically characterized by the wheelchair industry – may be enough to gain regulatory approval and avoid products liability suits, but not enough to avoid infringement. This puts an added constraint on 510(k) applicants seeking to design around De Novo predicates – the invisible force of products liability suits for redesigns of approved devices.

#### 9.4 CONCLUSION

Allowing De Novo or breakthrough device applicants to patent their devices’ special controls and performance characteristics creates an anticompetitive gauntlet for 510(k) device applicants. Those 510(k) applicants seeking to use De Novo or breakthrough devices as predicates are hemmed into either admitting their devices are “substantially equivalent” to their predicates – effectively an admission of patent infringement – or that they use different technological or performance characteristics, a regulatory concession sinking their own applications. These difficulties may be exacerbated in more complex cases involving standards essential patents, IP covering medical software, or design-arounds that raise products liability concerns. This cannot be what Congress intended when it opened the 510(k) pathway to De Novo devices. The FDA should consequently be warier about De Novo applicants that propose special controls or performance covered by the applicants’ own patents. If left unchecked, the future of medical regulation may turn not on innovation of devices’ safety and effectiveness, but strategic avoidance of others’ intellectual property.

<sup>75</sup> *Id.* at 981.

<sup>76</sup> *Id.*