G.R. No. 211850 ***(Zuneca Pharmaceutical and/or Akram Arain and/or Venus Araian, M.D., and Style of Zuneca Pharmaceutical v. Natrapharm, Inc.)***

Promulgated: September 8, 2020

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SEPARATE CONCURRING OPINION

GESMUNDO, *J.:*

> *The State shall protect and promote the right to health of the people and instill health consciousness among them.*[1]
>
> *The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health, manpower development, and research, responsive to the country's health needs and problems.*[2]

I concur with the *ponencia*. However, I am of the view that for the sake of public interest, the Court should not simply hand a verdict on this occasion, but also express its stand on how the relevant government institutions can move forward. The present decision carries the misfortune of allowing two different drugs with confusingly similar brand names to be sold in the market. This can lead to egregious consequences on public health and safety, as empirical data already show. There is thus a need to amend or supplement existing legislation and regulations to cushion against the decision's harmful effects on our People's wellbeing.

At the onset, it must be emphasized that the misfortune of this decision is not borne of the Court's subjective interpretation of the law, but brought about by its very letter. Section 159.1 of the Intellectual Property Code *(IPC)* is clear that a registered mark shall have no effect against any person who was using the mark in good faith for his business or enterprise before the filing date.[3] This provision, in turn, appears to have been derived from Article 16(1)

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[1] Article II, Sec. 15, 1987 Constitution.

[2] Article XIII, Sec. 12, 1987 Constitution.

[3] Sec. 159.1 of the IPC states in full:

159.1. Notwithstanding the provisions of Section 155 hereof, a registered mark shall have no effect against any person who, in good faith, before the filing date or the priority date, was using the mark for the purposes of his business or enterprise: Provided, That his right may only be transferred or assigned together with his enterprise or business or with that part of his enterprise or business in which the mark is used.

of the Agreement on Trade-Related Aspects of Intellectual Property Rights *(TRIPS),* which provides that the rights of a registered trademark owner "shall not prejudice any existing prior rights, nor shall they affect the possibility of Members making rights available on the basis of use."[4] The IPC was enacted in keeping with the country's commitment to international conventions, among which is the TRIPS to which it adhered to in 1995 following its entry into the World Trade Organization.[5] There is thus no gainsaying that the statute states what it intends. The rule is that where the law is clear and unambiguous, it must be taken to mean exactly what it says, and courts have no choice but to see to it that the mandate is obeyed.[6]

Alas, the brand names that the law requires the Court to uphold may have benign effects if they pertain to different goods, but not so when they are both prescription drugs. The names "Zynapse" and "Zynaps" are almost absolutely identical; the letter "e" in the former being a negligible element for differentiation. The concurrent availability of these drugs in the market poses a significant threat to consumer health. In fact, respondent Natrapharm pointed out that if a stroke patient who is supposed to take Zynapse *(citicoline)* mistakenly ingests Zynaps *(carbamazepine)* which is an anti-convulsant medication used to control all types of seizure disorders like epilepsy,[7] not only will he not be cured of stroke, he will also be exposed to the risk of suffering Stevens-Johnson syndrome. The latter, a side effect of *carbamazepine*, is a condition where a person suffers serious systemic body-wide allergic reaction with a characteristic rash that attacks and disfigures the mucous membrane.[8]

Medication errors are the most expected outcome in the coexistence of Zynapse and Zynaps in the market. The World Health Organization *(WHO)* adopted the United States Food and Drug Administration *(US FDA)* definition of "medication error" to mean "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health-care professional, patient or

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[4] Article 16(1) of the TRIPS states in full:
1. The owner of a registered trademark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed. The rights described above shall not prejudice any existing prior rights, nor shall they affect the possibility of Members making rights available on the basis of use.

[5] https://www.ipophil.gov.ph/news/the-intellectual-property-system-a-brief-history/ last accessed February 12, 2020.

[6] *Abakada Guro Party List v. Ermita*, 506 Phil. 1, 113 (2005).

[7] Decision, p. 3.

[8] Decision, p. 40.

consumer."[9] In its report entitled *The Philippines Health System Review*,[10] the WHO states that among the factors that contribute to medication errors in the Philippines is incorrect interpretation of the prescription or medication chart. Prescribing and dispensing errors, on the other hand, often occurred because of the unreadable handwriting of the doctor. The report shared a study conducted in public and private hospitals in Quezon City which found that 28% of the sampled patients could not read their doctor's prescriptions well, which led to medical consequences such as improper dosage and even death. Notably, another common cause of medication error reported in the Philippines is the existence of look-alike or sound-alike medication names. Some of the examples given were "Mesulid" versus "Mellaril," "Ceporex" versus "Leponex" and "EMB" versus "EMBR."[11]

Moreover, in a 2010 study[12] of a group of nurses at the Philippine Heart Center, it was revealed that medication errors are found in prescribing (90.85%), order processing (55.7%), dispensing (92.5%) and administering (85.4%). These errors were attributable to increased workload, interruptions or distractions, and high patient to nurse ratio. In a 2016 online article,[13] it was also reported that in the Philippines, 79% of patients experience at least one error during their medication period. Some of the identified causes were: (1) poor communication between healthcare providers; (2) when a physician does not make his patient clearly understand the prescribed medication; and (3) medication names and medical abbreviations that sound alike, which cause confusion and incorrect usage.

It is acknowledged, based on the studies mentioned above, that medication errors are not solely attributable to confusingly similar medication names. However, it is an area that the government can effectively regulate, *vis-à-vis* human factors such as poor communication among health providers and physicians' illegible handwriting. Allowing confusingly similar medication names to be sold in the market poses a direct challenge to the State's ability to fulfill its constitutional mandate to protect

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[9] "The Philippines Health System Review," Health Systems in Transition, Vol. 8, No. 2, page 243, World Health Organization, 2018, http://apps.searo.who.int/PDS_DOCS/B5438.pdf, last accessed February 12, 2020.

[10] Id.

[11] Id.

[12] Carino, Germin Dale, et al., Factors that Contribute to Medication Errors in the Philippine Heart Center (2010), abstract found in https://www.phc.gov.ph/Images/articles/Factors%20that%20Contribute%20to%20Medication%20Errors.pdf. See also Literatus, Zosimo, Medical errors in the Philippines, SunStar Cebu, https://www.sunstar.com.ph/article/1808499, both websites accessed on February 12, 2020.

[13] How Can Patients Prevent Medication Errors, The Philippine Star, December 13, 2016, https://www.pressreader.com/philippines/the-philippine-star/20161213/282600262514343, last accessed February 12, 2020.

and promote the right to health of the people.[14] Hence, government action is imperative. What is lacking in the law should be made up for by further legislation and regulation.

A good starting point would be to expand the regulatory powers of the Food and Drug Administration *(FDA)* to cover strict monitoring and registration of medication brand names.

A little bit of history is in order.

In 1963, Republic Act *(R.A.)* No. 3720 was passed, also known as the Food, Drug, and Cosmetic Act. The law declared it the policy of the State "to ensure safe and good quality supply of food, drug and cosmetic, and to regulate the production, sale, and traffic of the same to protect the health of the people." For that purpose, it created the FDA, which was tasked to administer and supervise the implementation of the law and rules and regulations that will be issued pursuant thereto. Later, Executive Order No. 851[15] was signed, reorganizing the then Ministry of Health. It abolished the FDA and created the Bureau of Food and Drug *(BFAD)* in its stead.

On November 17, 1986, BFAD Regulation No. 2 was issued, having for its subject the "Assignment of Brand Name and/or Generic Names for a Formulation of a Drug of Pharmaceutical Specialty." It provided that BFAD should issue a clearance for a particular brand name before it may be registered. Pertinent provisions of this regulation state:

> 1. All drugs and/or pharmaceutical specialties, whether imported or locally manufactured, shall be registered with the Bureau of Food and Drugs (BFAD) under their generic and/or brand name prior to local marketing.
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> 3. A drug manufacturer, toll/contract manufacturer, distributor, drug department or licensee can use a brand name and/or generic name for a given formulation of a drug or pharmaceutical specialty with a single active ingredient; Provided however, that brand name will not have an identical or similar name with those previously and/or already registered with this Office.
> 4. No imported drug or pharmaceutical specialty, though patented and/or registered in other countries, will be registered if there exists an identical or similar brand name already registered with BFAD.

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[14] Art. II, Section 15 of the 1987 Constitution states:

Sec. 15. The State shall protect and promote the right to health of the people and instill health consciousness among them.

[15] Executive Order No. 851, entitled "Reorganizing the Ministry of Health, Integrating the Components of Health Care Delivery into its Field Operations, and for Other Purposes," was signed on December 2, 1982.

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7. Every brand name of a drug or pharmaceutical specialty shall be submitted for name clearance to BFAD prior to registration. The purpose of the name clearance is to prevent similarity of the brand name with other previously registered drug products.
8. The general procedures for clearing brand names are:
   - 8.1. brand name must not be confusing in speech, in rhyme or in writing with other registered brand names.
   - 8.2. brand name must not be confusingly similar nor identical with the first syllables unless the middle syllables create distinctive appearance and sounds.
   - 8.3 brand name must be different either in prefix, middle or suffix syllables if applied to the different generic class of drugs or where the drugs have different indications to prevent confusion.
   - 8.4 brand name must not be identical or similar to INN (International Non-proprietary Names).
   - 8.5 brand name must not, in any way, conflict with the established guidelines as outlined in MOH Administrative Order No. 76 dated January 24, 1984.

However, on July 23, 1999, Bureau Circular No. 17, series of 1999 was issued, which dealt with the "Transfer of Processing of Brand Name Clearance for Pharmaceutical Products to the Intellectual Property Office *(IPO)*." The circular reads in full:

> To effect a centralized clearing house of all brand names used for consumer products, including foods, drugs, cosmetics and household hazardous substances, the Bureau of Food and Drugs will transfer the function of issuance of certificate of brand name clearance to the Intellectual Property Office (IPO). Such transfer will initially involve pharmaceutical products succeeded by other products generated by the Bureau.
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> All pharmaceutical companies are therefore advised to secure Certificate of Brand Name Clearance from the said Office to comply with the requirements for registration of branded pharmaceutical products as specified in the Guidelines for the Registration of Pharmaceutical Products issued under Bureau Circular No. 05, s. 1997.

BFAD, therefore, abdicated its authority to approve pharmaceutical brand names in favor of the IPO, and decided to rely on the IPO's issuance of a Certificate of Brand Name Clearance before it registers such name.

It is not clear from the facts whether Zuneca obtained clearance from the IPO before it was granted a Certificate of Product Registration by BFAD for Zynaps on April 15, 2003.[16] Nonetheless, there would not have been an

[16] Decision, p. 4.

issue, as there appears to be no similar-sounding pharmaceutical brand name that was registered with the fledgling IPO[17] at the time.

On June 21, 2005, the Secretary of the Department of Health (DOH), Francisco T. Duque III, issued Administrative Order *(A.O.)* No. 2005-0016, which had for its subject "General Policies and Guidelines Governing Brand Names of Products for Registration with the Bureau of Food and Drugs." Through this A.O., the DOH declared that "it is not the gatekeeper" in the regulation of brand names, as its mandate is *only* to "ensure the safety, efficacy and good quality of products applied for registration." The A.O. stated:

> This Department acknowledges that it is not the gatekeeper in the promotion and regulation of brand names which are often times being used as marketing tools, without any connection or relation whatsoever to the safety, efficacy and quality of the products. In issuing this Order, this Department, through BFAD, hereby reiterates and consistently adopts its mandate and responsibility to only ensure the safety, efficacy and good quality of products applied for registration.

A.O. No. 2005-0016 laid down guidelines that did away with the process of obtaining brand name clearances from the IPO. Instead, BFAD decided to rely on its own listing to determine whether a brand name being applied for is identical to one already registered, and consequently be denied registration. This is the regulation in effect at the time Natrapharm obtained its trademark registration with the IPO in 2007, and later a Certificate of Product Listing from the BFAD. One may wonder how or why BFAD registered Natrapharm's brand name, Zynapse, considering that it had already earlier registered an almost identical brand name, Zynaps, in the same product classification, *i.e.* drugs.[18]

The reason may lie in the fact that, consistent with its stand that it is not a "gatekeeper" of brand names, BFAD adopted a laidback approach in its regulation of pharmaceutical brand names. There is none of the traces of a stringent evaluation of a potential brand name *vis-à-vis* those already registered in terms of confusing similarity in speech, rhyme or writing, prefixes and syllables, among others, as was present in BFAD Regulation No. 2. While the latter regulation adopted the parameters "identical or

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[17] The Intellectual Property Code which established the Intellectual Property Office was approved on June 6, 1997, but took effect on January 1, 1998 in accordance with Section 241 thereof.

[18] A.O. 2005-0016 defines "product classification" as "the separate and distinct classification between and among food, cosmetic, drug, veterinary product, device, diagnostic reagents, and household hazardous substance. This means that the classification for food, etc. is separate and distinct from the classification for cosmetics and the others."

similar," the present regulation settled for "identical" and limited the grounds for rejection of a brand name to the following: 1) names that are identical to those already registered with the BFAD in the same product classification, and 2) names that are offensive, obscene, scandalous or otherwise contrary to public morals and policy.[19] More, A.O. No. 2005-0016 indicates a general deference to "proper authorities" who have a final say in the determination of who has a better right over a brand name.[20] Natrapharm's earlier registration of the Zynapse brand with the IPO may have provided sufficient sway for the BFAD to register the name regardless of its confusingly similarity with another name in its database.

It is disconcerting that through A.O. No. 2005-0016, the DOH limited the interpretation of its mandate and responsibility to ***only*** ensuring the "safety, efficacy and good quality of *products* applied for registration," without bearing in mind consumer safety that may be achieved when people are able to access the correct medicine without the element of confusion caused by similar brand names. Note should be taken of the fact that R.A. No. 3720, under which auspices A.O. No. 2005-0016 was created, also declared it the policy of the State "to protect the health of the people." To be sure, this encompasses not only consumers' safety resulting from safe, effective, and good quality pharmaceutical products in the market, but also consumers' safety arising from the minimization, if not elimination, of medication errors borne by confusingly similar drug names. This view gains more significance in light of past experiences where mistakes in the dispensation of medicine brought about by similar names put patients at risk. For example, the website of the Philippine College of Physicians[21] shared an undated narrative involving the FDA's registration of the same generic name for two (2) different drugs. Thus:

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[19] Section 2, A.O. No. 2005-0016.

[20] See the following provisions of A.O. No. 2005-0016:
Section 4. The acceptance by BFAD of the proposed brand name shall not be interpreted or construed as an approval, endorsement or representation that the applicant has the right or privilege to the use of the brand name so submitted.
Section 5. The applicant shall execute an affidavit of undertaking (a) to change the brand name so submitted should the proper authority decides with finality that he/she/it has no right to appropriate and utilize said brand name; and (b) to acknowledge and agree to indemnify and/or hold BFAD free and harmless against any and all third party claims arising from the acceptance of such brand name of the product for registration with BFAD. xxx
DISPUTES
Section 1. In the event that any interested party notifies BFAD in writing of any alleged prior or existing intellectual property right over the brand name of the product pending registration, BFAD shall immediately respond to said party, in writing, that intellectual property matters are beyond the legal mandate of BFAD and that their proper recourse should be from the IPO or the appropriate courts of competent jurisdiction.
Section 2. Under no circumstance shall the filing of any such notification be the reason or cause to suspend, delay, or otherwise adversely affect the processing of the application for, and the issuance of the CPR/CPL until and unless BFAD is restrained or enjoined by the proper authorities from doing so. In this instance, "proper authority" shall only pertain to the IPO or courts of law with competent jurisdiction over the said subject matter.

[21] https://www.pcp.org.ph/index.php/component/content/article?id=211:chapter-4-, last accessed on February 13, 2020.

A story of medication error in the hospital.

An oncologist wrote instructions on the hospital chart for the IV administration of the oncolytic drug mesna (brand name Uromitexan), but the nurse mistook it for the respiratory solution also called mesna (brand name Mistabron). The respiratory solution meant for nebulization was injected intravenously for a total of 8 doses over a period of 3 days until the error was discovered.

Patient was never told of the error by the attending physician and was, in fact, sent home on the same night. Some tests were ordered but these were never carried out. Drug industry help was sought on pharmaceutical physico-chemical information but they could not be contacted over the weekend.

The Philippine FDA was informed of the incident on Monday and they were surprised how they managed to register two drugs sharing the same name.

The doctor, in following the Philippine Generics Act of 1988 mandating that the doctor should write the generic name of a prescribed drug, was unclear about his responsibility to indicate the specific product trade name. The nurses (three shifts over three days) did not read the ampoule information prior to administration. The hospital pharmacist sent the ampoules to the floor without an accompanying box or product information leaflet. Patient could not be followed up. (emphasis supplied)

More than 40 years from the enactment of R.A. No. 3720, R.A. No. 9711 took effect. Otherwise known as "The Food and Drug Administration Act of 2009," the law aimed to strengthen and rationalize the regulatory capacity of the Bureau of Food and Drug, which was renamed as the Food and Drug Administration. The reinforced and more encompassing reach of the FDA's regulatory authority is reflected in Section 3 thereof, which declared it the policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to: (a) protect and promote the right to health of the Filipino people; and (b) help establish and maintain an effective health products regulatory system,[22] among others. Unfortunately, the FDA did not find it necessary to revisit A.O. No. 2005-0016, which is still the regulation currently in place with respect to pharmaceutical brand names subject of registration with the FDA. BFAD Regulation No. 2 would have done a better job in minimizing confusingly similar brand names in the market.

[22] Sec. 3, R.A. No. 9711.

At this point, it would be worthwhile to discuss how certain jurisdictions have taken practical measures to minimize medication errors by regulating proposed drug names.

In December 1999, the Institute of Medicine, a group involved in the examination of public health policy and identifying the medical care, research and education issues in the United States, issued a report entitled *To Err is Human: Building a Safer Health System.* It revealed that an estimated 44,000 to 98,000 people die annually from medical errors, more than the deaths that occur as a result of motor vehicle accidents, breast cancer, or AIDS. It recommended, among others, for the US FDA to increase its attention to public safety, and exert effort to eliminate similar-sounding drug names, as well as confusing labels and packaging that foster mistakes.[23] This and similar other reports that came after it, prompted the US government to enact new laws, and the US FDA to review proposed pharmaceutical trademarks more rigorously and issue new regulations.[24]

At present, the US FDA's approval of medication trade names is mandatory and independent from registration with the US Patent and Trade Office *(USPTO).*[25] The US FDA compares proposed product names only with product names that it had previously approved, and does not consider the USPTO Register. This has led to scenarios where an owner of a valid trademark registration cannot use it because another party with junior trademark rights was first to obtain US FDA approval for the corresponding product name.[26] In the recent guidelines it issued,[27] the US FDA requires applicants to submit, among others, two proposed proprietary names for review, their intended pronunciation and an explanation of the derivation of the proposed proprietary name, if any.[28] The safety evaluation of a proposed proprietary name involves multiple methods to identify possibly problematic ones, including a preliminary screening to identify common errors, an orthographic or phonological similarity assessment, and drug database searches.[29]

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[23] Havens, Debra Hardy, et al., "To Err is Human": A Report from the Institute of Medicine, Legislative News, March/April 2000, https://www.jpedhc.org/article/S0891-5245(00)70009-5/pdf, last accessed February 13, 2020.

[24] Pharma: Regulatory Encroachments on Trademark Rights—Is This the Future for Brands? INTABulletin, Vol. 73, No. 2, February 1, 2018, https://www.inta.org/INTABulletin/Pages/Committee_Update_7302.aspx, last accessed February 13, 2020.

[25] Litowitz, Robert, et al., Procedures and Strategies for Pharmaceutical Brands: United States, World Trademark Review, September 6, 2016, https://www.worldtrademarkreview.com/procedures-and-strategies-pharmaceutical- brands-united-states, last accessed on February 13, 2020.

[26] Strobos, Jur, et al., Procedures and strategies for pharmaceutical brands: United States, World Trademark Review, March 13, 2018, https://www.worldtrademarkreview.com/anti-counterfeiting/procedures-and-strategies-pharmaceutical-brands-united-states, last accessed February 13, 2020.

[27] See Contents of a Complete Submission for the Evaluation of Proprietary Names—Guidance for Industry, April 2016, https://www.fda.gov/media/72144/download, last accessed February 13, 2020.

[28] Id. at 10.

[29] Id. at 5.

Similar regulations may be found in Canada and the European Union.

Since the 1990s, there had been concern in Canada with the growing number of drug names that looked and sounded alike, which could have adverse effects on public health and safety. However, there was doubt whether Canada's Food and Drugs Act and related regulations provide legal authority to enforce prohibitions on the use of look-alike/sound-alike trademarks. In 2014, the Food and Drug Regulations were amended by clarifying that Health Canada[30] had authority to consider brand names and adjudicate the question of whether there is likelihood that the proposed drug will be mistaken for a prescription drug in the market due to resemblance between their brand names. Health Canada was given authority to refuse to authorize the sale of a drug if it decides that there is likelihood that the proposed brand name will be mistaken for the name of an existing drug.[31]

Lastly, in the European Union, the European Medicines Agency *(EMA)* is responsible for evaluating the safety of medical products. Within this agency, the review of brand names is assessed by the Name Review Group *(NRG),* which was created in 1999 with the objective of ensuring that all medicines available in the EU market are safe, effective, and of high quality. Thus, the NRG may refuse a name which it believes poses a significant risk of generating confusion with marketed medicines, and even medicine products that have been revoked or withdrawn from the market within the five (5)-year period preceding the application submission.[32]

Literature suggests that the above-discussed regulations are not perfect and may be improved in many respects. But the underlying consideration should be the very existence of the effort to regulate, since the danger of medical errors brought about by confusingly similar drug names in the market is very real and cannot be ignored. A mechanism within our own FDA that polices drug names sought to be registered by local manufacturers and importers of pharmaceutical products is essential and serves not only to implement the State policy to protect consumers against

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[30] Health Canada is the Federal department responsible for helping Canadians maintain and improve their health. Source: https://www.canada.ca/en/health-canada/corporate/about-health-canada.html, last accessed February 14, 2020.

[31] Pharmaceutical Regulatory Encroachments on Trademark Rights—The Canadian Perspective, INTABulletin, Vol. 73, No. 8, May 1, 2018, https://www.inta.org/INTABulletin/Pages/PharmaRegulatoryEncroachmentsonTrademarkRights7308.aspx, last accessed on February 13, 2020.

[32] Pharmaceutical Regulatory Encroachments on Trademark Rights—The European Union Perspective, INTABulletin, Vol. 73, No. 10, June 15, 2018, https://www.inta.org/INTABulletin/Pages/PharmaceuticalRegulatoryEncroachmentsonTrademarkRightsTheEuropeanUnionPerspective7310.aspx, last accessed on February 13, 2020.

hazards to health and safety,[33] but also the constitutional mandate for the State to promote the right to health of the people[34] and establish and maintain an effective food and drug regulatory system.[35]

There is also room for our Intellectual Property Law to be improved in light of the compelling issue of medical errors brought about by similar drug names. The legislature can take a proactive stance by including as parameter for registrability of a pharmaceutical mark its confusing similarity with marks associated with pharmaceutical products already available in the market. A stricter rule in the evaluation of pharmaceutical marks is justified by the serious and disastrous health consequences arising from confusion by both health practitioners and consumers in the prescription, dispensation, and use of similarly named drugs.

Medications are the cornerstone of care provision. The safe use of medications can improve and save the lives of millions, but errors in the use of these substances can lead to equally significant consequences. Apart from harming people physically and psychologically, and in some cases even taking their lives, medication errors also lead to consequences beyond what money can repair. They can seriously damage public confidence and trust in medical services, and they affect the whole of society through lower productivity and decreased levels of population health.[36] It is thus necessary for the government to step up efforts to identify and minimize, if not eradicate, medication errors through, among others, the regulation of drug names. This may be done by amending legislation and formulating guidelines for the purpose. But since either of this may take time to put in place, the FDA and IPO may start by updating and strengthening their respective databases of registered pharmaceutical products to deter applicants for new drugs from choosing a name similar to one already existing in the market.

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[33] Article 2(a) of R.A. No. 7394, otherwise known as the Consumer Act of the Philippines, states:
ARTICLE 2. Declaration of Basic Policy. — It is the policy of the State to protect the interests of the consumer, promote his general welfare and to establish standards of conduct for business and industry. Towards this end, the State shall implement measures to achieve the following objectives:
a) protection against hazards to health and safety;

[34] Art. II, Sec. 15 of the 1987 Constitution.

[35] Art. XIII, Sec. 12 of the 1987 Constitution states:
Section 12. The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health, manpower development, and research, responsive to the country's health needs and problems.

[36] Salmasi, Shahrzad, et al., Medication Errors in the Southeast Asian Countries: A Systematic Review, published online September 4, 2015, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4560405/, last accessed on February 13, 2020.

Moreover, I agree with the *ponencia's* directive that the parties should print statements in their respective packaging that would inform stakeholders of the function of the medications involved and what they are used for, and for the FDA to monitor the parties' continuing compliance with the directive. This is a necessary consequence of the failure of our laws to address the circumstances at hand. We have held that when the law has gaps which tend to get in the way of achieving its purpose, the Court is allowed to fill the open spaces therein.[37]

R.A. No. 9711 declared it the policy of the State to promote the right to health of the Filipino people and establish an effective health products regulatory system in the country. This will not be achieved with the current FDA practice that prioritizes the availability of "safe, effective, and good quality pharmaceutical products," while overlooking the potentially adverse consequences on consumers' health of confusingly similar drug names. It is on these occasions that the Court may construe a law by issuing resolutions and/or guidelines in applying it. The purpose is to delineate what the law requires, including prudence and circumspection in its enforcement, or to assist a government agency in its implementation.[38]

Finally, in deciding cases, it is settled that the Court does not matter-of- factly apply and interpret laws in a vacuum. Rather, laws are interpreted always in the context of the peculiar factual situation of each case. All the attendant circumstances are taken in their totality so that justice can be rationally and fairly dispensed, in this case, not only to the parties but also to the Filipino people who are to bear the impact of this decision.[39]

Accordingly, I vote to **PARTLY GRANT** the petition.

ALEXANDER G. GESMUNDO
Associate Justice

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[37] *Re: Resolution Granting Automatic Permanent Total Disability Benefits to Heirs of Justices and Judges Who Die in Actual Service),* 486 Phil. 148, 156 (2004). See also *Floresca v. Philex Mining Corporation*, 220 Phil. 533, 559 (1985).
[38] Id. at 156-157.
[39] *Philippines Today, Inc. v. National Labor Relations Commission*, 334 Phil. 854, 880 (1997).